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Exhibit 61

	Page 432
1	IN THE CIRCUIT COURT OF THE 11TH JUDICIAL CIRCUIT
	IN AND FOR MIAMI-DADE COUNTY, FLORIDA
2	CIRCUIT CIVIL DIVISION
3	CASE NO. 2019-017627-CA-01
4	
5	ROBERT A. SUGARMAN, Individually
	and as Personal Representative of the
6	Estate of MARILYN WENDY SESKIN,
7	Plaintiff,
8	-vs-
9	
	JOHNSON & JOHNSON; JOHNSON & JOHNSON
10	CONSUMER, INC., f/k/a JOHNSON & JOHNSON
	CONSUMER COMPANIES, INC.; and PUBLIX
11	SUPER MARKETS, INC.,
12	Defendants.
	/
13	
14	TRANSCRIPT OF JURY TRIAL PROCEEDINGS
15	Volume 3
	Pages 432 - 573
16	
17	MIAMI-DADE COURTHOUSE
	73 W. FLAGLER STREET
18	MIAMI, FL 33130
	Tuesday, February 13, 2024
19	9:33 a.m 12:13 p.m.
20	
21	The above-entitled cause came on for trial
22	before the Honorable William Thomas, Circuit Court
23	Judge, taken before Elizabeth Cordoba, RMR, CRR, FPR,
24	and Notary Public in and for the State of Florida at
25	Large.

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Page 436 Thereupon, the proceedings continued from Volume 2 at 1 2 9:33 a.m.: THE COURT: I'm told we have five of ten 3 So it's 9:33. So I don't know if that's a 4 5 sign of something. 6 So what can we take up while we're waiting for 7 the other jurors? MR. OLIVER: Your Honor, last night I called 8 9 Ms. Brown and let her know that as we left the courthouse the bailiff said that -- I believe the 10 11 man's name is Juror Ruiz, disclosed that he 12 recognized or knew my local counsel, Mr. Reyes. So I 13 talked to Mr. Reyes about that. I told Ms. Brown. And I said we are going to raise it with the Judge 14 15 because the man may need to be questioned, and that I 16 am raising it with the Judge. I talked to her. I 17 said, Look, it's y'alls call. 18 THE COURT: Okay. I don't know why the bailiff 19 is saying that to you. Those aren't conversations 2.0 that you should be having with the bailiff. But it 2.1 is not my bailiff so he is helping me. So I have got 22 to be thankful that he's helping me. 23 Yes. The gentleman did approach me as I was 24 going into the elevator as well. And I told him, I

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said, I cannot speak -- I keep saying to everybody

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Page 437 1 the same thing, I cannot speak to you. The lawyers 2 must be present every time. But he -- but even though I said that, he did say, But what if I know 3 one of the lawyers? Now, he didn't give me the 4 5 specificity that you just communicated. 6 MR. OLIVER: That's it. 7 THE COURT: He said, What if I know one of the lawyers? And, of course, I was thinking, Well, you 8 9 were sitting in the room the whole time, and he was 10 sitting at the table. And we asked, Do you know any 11 of the parties? And so, I mean, we have to inquire. 12 But do you know him? 13 MR. REYES: I know of him. What does that mean? 14 THE COURT: MR. REYES: 15 Good morning. Nick Reyes, for the 16 So, I mean, as you know, Miami private 17 school community is a small community. I'm guessing he went to either Columbus or Belen. I went to 18 19 Columbus. They are both private schools. He's older 2.0 than me. I don't know how I know him. 2.1 Do you have his phone number? THE COURT: 22 I don't have his phone number --MR. REYES: THE COURT: Are you Facebook friends or 23 24 anything like that? 25 MR. REYES: I don't think we're Facebook

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friends. I don't use Facebook. We are definitely not Instagram friends. I was surprised to hear that he had two kids. I don't think he knows that I have children. We're just familiar. I don't know how we are familiar, but we are familiar with each other.

I thought -- I mean, it was years ago. So when I got up and said my name and he didn't say anything, I was questioning whether it was even him that I knew. I thought maybe he didn't recognize me. So, you know, I wasn't sure.

THE COURT: Well, I don't know if -- and by the way, I don't know if it matters if -- I mean, when we ask the question, Do you know any of the lawyers, that doesn't mean, okay, oh, we live in the same neighborhood.

MR. REYES: Absolutely.

THE COURT: It means, do you have regular contact with these people? Do you -- are you online friends? Do you have a personal relationship?

Meaning, you have their cell number, you know their spouse, you know their -- it's that type of thing.

Somebody did that one time when I was -- I remember I was a brand-new lawyer and during a trial, and somebody -- the judge asked, Do any of you know any of the lawyers? And the person raised their hand

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and said, Oh, yeah, I know him. And the judge looked at me, and I said, I don't know this guy. And we went sidebar, and come to find out, the person happened to have seen me -- I frequent a spot that that person frequents, and so the person was saying, Oh, I know him. No. We never spoke, you know.

And so this is a little different because you may have gone to the same school, but let's bring him in and let's ask him.

Rod, can you see if he's here? I didn't see him outside so I don't know if he's here.

MR. REYES: And, for the record, I think he's much older than I am. We weren't in the same class.

THE COURT: Do you remember what his name was?

MR. OLIVER: I think it's Mr. Ruiz.

THE COURT: Francisco Ruiz. See if he is here and then we'll bring him in and we'll ask whether or not there -- it doesn't sound like there's an issue.

I always love it. I think everybody decides to reveal things once they get selected.

MR. OLIVER: Well, Judge, we thought that, too.

THE COURT: Like, the lady who said, Oh, my

English not very good, but -- and she waited and said

you never gave me an opportunity to say I can't be

here for two weeks.

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Page 440 1 MR. OLIVER: I did think that was kind of 2 funny. We do have objections to each other's slides. 3 THE COURT: Oh. Let's talk about -- for 4 5 opening? Let's start with plaintiff's first because 6 -- you go first. 7 MR. OLIVER: Okay. No. I mean --8 MS. BROWN: Yes, yes, yes. Okay. Your Honor, 9 actually, I only have one objection --10 THE COURT: Okay. 11 MS. BROWN: -- to one document, which is --12 THE COURT: Can I just see the document? 13 MS. BROWN: Absolutely. May I approach? 14 THE COURT: Yes, ma'am. It's an Imerys document, Your 15 MS. BROWN: 16 Honor. It's not a Johnson & Johnson document. 17 it's a draft -- I don't know if it's a draft speech 18 or something from the file. 19 THE COURT: It's a what? 20 MS. BROWN: I don't know if it's a draft speech 21 from the documents of another company's files. And, 22 of course, Your Honor, and the law, was clear, that 23 the first -- before they can start putting in hearsay 24 documents under the conspiracy exception to the 25 hearsay rule, they have to establish the existence of

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a conspiracy using non-hearsay documents. And so they would have to lay the predicate, Your Honor.

So putting this up in opening before a conspiracy hasn't even been established, much less one that would permit this internal document that didn't go to J&J. They would have to show it was in furtherance of a conspiracy that they haven't even established. It's not admissible.

MR. OLIVER: So, Your Honor, my response to that is pretty simple. I don't think I view the rule the same way as Ms. Brown does, but what I did is I put together a packet for Your Honor and, conveniently, I didn't bring it to court. I forgot it. But it has a series of documents that establish the conspiracy, and I was going to make a proffer of it. What is in that packet, and what is coming, is J&J's agreement to support the Cosmetic Toiletries and Fragrances Association. And then it has a series of five documents showing that company or its predecessor interest.

(Juror Ruiz entered the courtroom.)

THE COURT: All right. Sir, come forward, please.

We were just talking -- I was explaining to the lawyers that you indicated yesterday that you knew

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1	one of the lawyers. Which lawyer do you think you
2	know?
3	JUROR RUIZ: He is not here today. Oh, there
4	he is.
5	THE COURT: Okay.
6	JUROR RUIZ: I don't know why. I know him from
7	somewhere.
8	THE COURT: You know him from somewhere. Do
9	you know where you know him from?
10	JUROR RUIZ: I don't know, man. I just
11	THE COURT: Let me ask it this way: Do you
12	have his cell number?
13	JUROR RUIZ: No.
14	THE COURT: Are you online friends?
15	JUROR RUIZ: No, no.
16	THE COURT: Have you ever been to his home?
17	JUROR RUIZ: No.
18	THE COURT: Do you have any personal
19	relationship with him?
20	JUROR RUIZ: Not that I know of, no. That's
21	what I am saying, I know of him.
22	THE COURT: He looks familiar? It's Miami.
23	Okay.
24	All right. Thank you so much, Mr. Ruiz.
25	JUROR RUIZ: Thanks.

Page 443 1 (Juror Ruiz exited the courtroom.) 2 THE COURT: You were saying, sir? 3 MR. OLIVER: I forgot where I was. I have a proffer, and it's going to have multiple documents 5 showing Imerys and Luzenac and Johnson & Johnson working together through the CTFA. 6 7 In fact, that very document establishes -- it says Johnson & Johnson was working with us, and we 8 9 were doing this together and we have considerable 10 input, Johnson & Johnson has considerable influence 11 on the CTFA, which is the organization through which 12 we allege that these two companies engaged in a 13 conspiracy to commit a tortious act. So my position is, you know, if I want to run 14 15 the risk that Your Honor later says it's not in, then 16 that's my risk to run. I will say that if Your Honor 17 wants to sustain the objection --18 THE COURT: Well, it is not your risk because 19 if I -- if I allow it and then I -- I'm sorry, if I 20 allow you to use it during opening and then I exclude 2.1 it during the case, then all the information that is 22 in there is already out. The jury has already heard 23 And that, to me, is a problem. 24 So I'm sustaining the objection. Remove the

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slide and you can use it if we get to the point where

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you're able to establish a predicate, but I'm not going to allow it to be used in evidence.

MR. OLIVER: Your Honor, I do want to ask about that. If I give you the proffer, will you look at that beforehand, like, you know, after this? It's not that much stuff. Is that something we can do?

THE COURT: You mean that would change my ruling as to opening?

MR. OLIVER: No, not that it would change ruling as to opening. I'm talking about instead of trying to do this through a witness, I'm asking, if I show you these documents, will you review them and make a proffer to establish this is enough of a predicate to introduce the documents with the witness.

THE COURT: I'm sorry. Forgive me. I'm not sure what you are asking me to do. You're asking me to read your proffer and then conclude that the proffer is sufficient to introduce the documents into evidence?

MR. OLIVER: Yes. Or not. It's up to you. I mean, I've done that before and judges say, okay, you're making an offer of proof.

THE COURT: Why don't you just do it -- I could do it with -- why don't you just do it through the

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Page 445 1 witnesses, and then if there is an objection when you 2 attempt to introduce the documents, I either sustain or overrule the objection. 3 4 MR. OLIVER: Okay. 5 THE COURT: As compared to me taking time out and reading a proffer and then telling you -- and 6 7 what happens if I tell you it's not? Then you're going to come back -- you want to edit it and come 8 9 back, and say, read it now and read it again and add 10 some new stuff. 11 MR. OLIVER: Okay. I understand. 12 In other words, you would get one THE COURT: 13 shot at doing it at the trial, whereas you would get multiple shots of doing it if we did it the other 14 15 way. 16 MR. OLIVER: Okay. I think that was her only 17 objection to my slide deck. 18 MS. BROWN: Thank you, Your Honor. Thank you 19 very much. 20 THE COURT: All right. Did you have objections 21 to their slides, sir, their presentation? 22 MR. OLIVER: I do. So let me go through this 23 first page. Five, you agreed to change that? 24 MS. BROWN: I do. 25 MR. OLIVER: So our first objection is --

Page 446 1 MS. BROWN: Your Honor, would you like a copy 2 of this? THE COURT: Please. 3 MR. OLIVER: It would probably be a good idea. 4 5 Our first objection is on Slide 17. defense counsel intends to highlight the genetic risk 6 7 factors. I don't mind her listing genetics as a risk factor, but they are going back to this and the Court 8 9 has already ruled they don't have expert support for 10 this theory. They are going to use --11 THE COURT: What theory, sir? 12 MR. OLIVER: -- the theory that Dr. Seskin had 13 a genetic risk for ovarian cancer that she didn't 14 have. Now, what they are going to use, I believe, is 15 her own notes. 16 Is that what these are? I can't see. 17 MS. BROWN: Yes. I'm happy to explain. MR. OLIVER: Well, I want to -- let me do this. 18 19 Okay? 20 So these are her own notes. And we talked 21 about the fact that she is a doctor, and we don't 22 need to do that. And so what I was going to do in 23 opening is simply say, one time, Marilyn Seskin was 24 an anesthesiologist when she was alive. 25 THE COURT: We are talking about this one here.

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MR. OLIVER: Yeah, these two.

2 THE COURT: Okay.

> MR. OLIVER: So I was going to say, she is an anesthesiologist. I'm not going to call her Dr. Seskin. I am going to call her Marilyn Seskin, right, because of the issue Your Honor raised, and that is fine with us.

What they've done in their argument is put Dr. Seskin is making these conclusions. Dr. Seskin didn't have the expertise in this. was an anesthesiologist, and her husband is going to testify she thought during the course of her cancer treatments many different things could have caused her cancer. She was desperate to find out what it was, and they are going to highlight this.

So we think it is argumentative, and we think that it is more prejudicial than probative. And the only way that it comes in, in my opinion, is if they lay a foundation through one of our experts or somebody on the stand. If they want to do that then, maybe.

But in opening, I don't think --

THE COURT: I don't understand, sir. Are you telling me that if there is an individual who is diagnosed with cancer, and they believe that these

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are the reasons why I may have gotten cancer and they write them down, they cannot -- the other side cannot ask whether or not -- what were the factors that you thought caused you to get cancer?

And by the way, not saying that she has some expertise, but she just happens to be a doctor, and that is why I asked that question, why are we calling her doctor.

MR. OLIVER: Right.

THE COURT: But she is the plaintiff, and she just simply says, Well, I thought maybe it was because I used bleach, or I thought it was because I did this. Why is that not admissible?

MR. OLIVER: On the stand, I am pretty sure I agree with you, but in the form of this slide with no background on Dr. Seskin and what this is, which would be opening, that's what I have a problem with.

If they lay the foundation through a witness, and they want to go to my client, Mr. Sugarman, and say, Bob, are these Marilyn's notes and this is what she said, they can do that. I am not objecting to that.

What I am objecting to is having a slide that says, Dr. Seskin concluded her own --

THE COURT: And I would agree with that

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because -- and, again, I have a problem with you all calling her doctor. Obviously, that seemed to be only my issue, because nobody else brought it up, because you both were referring to her as Dr. Seskin.

MR. OLIVER: Sure.

THE COURT: And if I was on -- if I was your client, you wouldn't refer to me as Judge Thomas. would be William Thomas. The fact that I am a judge doesn't mean -- and the fact that she is a doctor, I think, complicates everything because now it is exactly what you just said right here.

They put up their -- but everybody is calling her Dr. Seskin, and the problem is, is that there is some suggestion that maybe she had some special knowledge or some training as to this, when she was an anesthesiologist. She didn't study cancer.

What do you want to say in response?

MS. BROWN: Thank you, Judge. I just don't want to be disrespectful. The reason I am calling her Dr. Seskin is because that is how she referred to herself. That is how they took the deposition of the treater, asking about Dr. Seskin. So it is going to play, and I don't want a juror to think I am somehow disrespecting her when they, in asking the treater's questions, refer to her as "doctor."

Page 450 1 And so I understand it complicates things a 2 little bit, and, frankly, it probably cuts against me, but this is a woman who went to medical school 3 and was an anesthesiologist, and I just feel, you 4 5 know --6 THE COURT: But she didn't study -- I always 7 say to this: You are a lawyer. You went to law school. 8 9 MS. BROWN: Right. 10 THE COURT: And if I ask you to outline -- if 11 it was a criminal case -- I don't know your 12 background. 13 MS. BROWN: I don't know anything about criminal law. 14 15 THE COURT: So if I ask you to all of a sudden 16 to start outlining, you would basically say, I really 17 can't. 18 MS. BROWN: Sure. 19 I can give you some general THE COURT: 20 thoughts because I went to law school, I took 21 Criminal Law I, Criminal Procedure, Criminal Law II, 22 but I can't do that with any type of authority. don't know if this is any different than that. 23 is a doctor. 24 25 MS. BROWN: I understand.

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Page 451 THE COURT: 1 She is medically trained. 2 MS. BROWN: Sure. 3 THE COURT: But that doesn't necessarily mean -- and, by the way, I always say, lawyers who 4 5 basically take anything that comes through the door, I always think they are waiting to be sued because 6 7 the reality is, is that you can't possibly know all these areas of law. 8 9 MS. BROWN: Sure. 10 THE COURT: And we have all been in situations where we got a call from friends who said, Oh, I had 11 12 I don't know anything what you are talking this. 13 about, you know. I just don't. I have no idea. 14 I don't do real estate. MS. BROWN: 15 THE COURT: I don't do probate, you know, and 16 things like that. 17 MS. BROWN: Sure. 18 THE COURT: So I don't know how we solve this. 19 MS. BROWN: I will put "Marilyn Seskin." 2.0 just didn't want to be disrespectful. 21 THE COURT: There you go. 22 I mean, we have the same objection MR. OLIVER: 23 as to her notes on that in the opening. 24 I am allowing the notes because you THE COURT: 25 have a good-faith basis to believe they are going to

	Page 452
1	come into evidence, and I am going to allow them to
2	come in.
3	MR. OLIVER: Okay.
4	MS. BROWN: Yes, Your Honor.
5	MR. OLIVER: I assume you will change
6	Dr. Seskin throughout. I think that is where it was.
7	MS. BROWN: I would be glad to, sure. You want
8	me to call her Marilyn Seskin? Is that where we are
9	at?
10	MR. OLIVER: That is her name, yeah. It is
11	going to come out she is a doctor.
12	MS. BROWN: I understand.
13	MR. OLIVER: That is where we are.
14	MS. BROWN: I understand.
15	MR. OLIVER: So, Your Honor, they have used
16	Dr. Slomovitz in Slide 31.
17	THE COURT: What number?
18	MR. OLIVER: It's Slide 31. Remember,
19	Dr. Slomovitz is a witness that you excluded, and
20	this is the issue that I was concerned about when you
21	excluded him.
22	I understand Your Honor said, Hey, the article
23	is in. My concern was that defendants are going to
24	make a big deal that one of her treating physicians,
25	who cannot testify for reasons that they caused, they

Page 453 1 are going to now use that as an endorsement. 2 what he wrote. Look what he wrote. 3 If they are going to use the article with the witness, fine. But I don't think it is fair to put 4 5 up and make an argument -- again, this is opening, and this is argumentative -- that her treating 6 7 physician said something or endorsed something that 8 he didn't say or endorse. 9 THE COURT: Did he not -- so these notes here, 10 he did not say these things? 11 MR. OLIVER: No, no. That's --12 THE COURT: Oh, that is separate. 13 MR. OLIVER: That is something separate. This 14 is the guy who wrote the article that you excluded. 15 You excluded him, not the article. Okay? And, I 16 mean, I assume they are going to say, Look, her 17 treating physician, all through this article --18 Well, wait. We should ask what she THE COURT: 19 is going say before we conclude --2.0 MS. BROWN: Thank you, Your Honor. 21 So these --22 THE COURT: One minute, please. 2.3 MS. BROWN: Sure. 24 We are missing Richard Gonzalez. THE COURT:

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MR. OLIVER: Is that our traveler, the one who

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	Page 454
1	had travel problems?
2	MS. DIOLOMBI: Yes.
3	MR. OLIVER: That is the traveler.
4	THE COURT: And I predicted that. And I
5	said and it is unfortunate, but and Carlos has
6	been calling him and not getting a response.
7	MS. BROWN: He is probably in transit.
8	THE COURT: Well, he may be stuck in transit,
9	or he is stuck on, I just can't. I just don't have
10	the money. I can't get here.
11	MS. BROWN: I understand.
12	THE COURT: And so he may have made the
13	decision for us. I don't know.
14	MR. OLIVER: We don't have an objection to him
15	being
16	THE COURT: Replaced.
17	MR. OLIVER: dismissed for that reason or
18	replaced.
19	MS. BROWN: We would like to give him five or
20	ten more minutes. He seemed very
21	THE COURT: No, we are going to do this. We
22	will give him five or ten more minutes.
23	MR. OLIVER: I don't have any problem with
24	that, Judge.
25	THE COURT: I forgot. You were going to tell

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us how or why you were going to use the slide.

MS. BROWN: Thanks, Your Honor. And I fully understand the Court's ruling on Dr. Slomovitz.

There is no doubt, though, that he was a treating physician, and the medical records that he authored, Counsel wants my agreement to stipulate they will come into the case.

So that part will come in, and Your Honor said certainly his published literature will come in. So on this slide, I am just going to say, You are going to get the hear from one treating physician.

I'm sorry --

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THE COURT: Oh, he is close by. I am sorry.

MR. OLIVER: I don't know that the published literature comes in.

MS. BROWN: Hang on.

So on this slide, I will talk about the testimony coming from Dr. Morrissey, and you are going to get to see a publication that one of her treating physicians wrote on this topic.

That is all I am going to say.

THE COURT: I don't have a problem with that.

MS. BROWN: Thanks.

THE COURT: Next.

MR. OLIVER: My next objection was Number 33.

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I'm not worried about that. It is not the end of the world.

Your Honor, Slide 50, again, this is a reference -- so Slide 50 says, pure scientist -- science methodology and data cannot trusted, and this is about that doctor yesterday that we had an MIL on. His name is Dr. Saed.

Our experts -- while every expert put this stuff on their reliance list, what happens is a body of literature develops, and all of them, theirs, ours, they update it, right?

We are not coming in here and saying anything about Dr. Saed. He is not in this case. And they have an entire slide that focuses on articles and elements that are criticizing Dr. Saed's work, but he is not here. I mean, under 90.403 in opening, I don't see how that is probative.

THE COURT: Can I ask, is anyone going to be making reference to Dr. Saed's work?

MR. OLIVER: None of our experts are. What I suspect -- and she will speak for herself -- what I suspect they are going to do is make a big deal about the fact that Dr. Saed did this and Dr. Saed did that, and we are going to look at the jury and say, We didn't hire him for a reason, and we are not

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Page 457 1 talking about his studies for a reason. 2 What did Dr. Saed do? THE COURT: MR. OLIVER: I don't think he did anything. 3 I will be glad to explain. So the 4 MS. BROWN: 5 slide before Your Honor sort of sets up the issue, 6 which is that there has been a series of cell studies 7 that say, Look, if we take talcum powder and put it 8 on cells, do we see precancerous changes? They uniformly say no. Until we get to this Harper and 9 10 Saed study that was actually funded by Ms. O'Dell's 11 law firm. 12 So they fund him to do the study. He concludes 13 malignant transformation, and the peer reviewers who get the article before he is trying to publish it, 14 15 have comments that say, this is outrageous. This is 16 not supported by the data. 17 THE COURT: So can I pause? 18 MS. BROWN: Yeah. Who is going to introduce the fact 19 THE COURT: 20 that Dr. Saed did this study and what the findings of 21 that study were? Who is introducing that? 22 It's on their expert's reliance MS. BROWN: 23 list. And I think what Your Honor said yesterday is 24 you can't just, like, you know, decide not to do it.

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Right? That is fair across. You put this on your

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reliance list.

THE COURT: No, no, no. You're right. say that. But what I said, at least the context that I remember saying it in, is that if your expert has already reviewed it and said that they relied upon it, you don't get to then come in and say, Well, just don't mention that.

MS. BROWN: Correct.

THE COURT: Okay. You have already testified in your report or in deposition, I reviewed it and I relied upon it. You don't get to disavow it --

MS. BROWN: Correct.

THE COURT: -- once you go to trial. So do you have testimony at the deposition or in the expert report that this was reviewed by this expert -- I mean by a witness, and that that witness testified that they relied upon it?

MS. BROWN: Yes, sir. Dr. Plunkett, first witness coming up today, has it in her expert report and was crossed on it in a deposition. And so I will cross her on it. And then I have my own expert who reviewed it in connection with all the cell studies who is going to come and say why it is an outlier from all the other cell studies.

MS. O'DELL: Good morning, Your Honor.

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Dr. Plunkett did review it and she has been cross-examined on it. She is not going to mention it in this trial, nor is Dr. Ness. It's part of the broader body of literature, as Mr. Oliver said.

THE COURT: But there is a difference between --

MS. O'DELL: I understand.

THE COURT: -- there's a difference between reviewing it and relied upon it. You can review a lot of things, but if you just looked at it and then you didn't comment on it, didn't rely upon it, it didn't form a basis of your opinion, I personally don't understand why it is relevant and probative to anything. But if you testify that you relied upon it, and this is what -- this is how it's formed your ultimate opinions in the case, then I think it's fair game.

MS. O'DELL: Well, Your Honor, definitely it is mentioned in Dr. Plunkett's report. I agree with Ms. Brown on that. She has been examined on it in deposition.

Here is the concern is that these are peer-reviewed comments that were -- so when Dr. Saed submitted his article to a journal, there were peer reviewers that were confidential. They provided

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comments. They were highly critical. They have been produced in litigation. Dr. Plunkett has not seen those comments. It's not her article. It's like a whole sideshow for this article that they are not going to mention. So it makes it a trial within a trial because --

THE COURT: I'm sorry. Did they not ask -during the deposition, they did not ask about the comments and the peer-reviewed comments that flowed from those findings?

MS. O'DELL: They did, I'm sorry, yes. been asked about those, but my point is there were many peer-reviewed comments. She doesn't have access She is going to ask about it out of the blue that there are these criticisms. She doesn't know what the state of the manuscript was at the time these comments were made, how it was different from what was actually published, which is all she's seen. So it's an absolute sideshow.

So the -- sort of the prejudice and the time outweighs any probative --

THE COURT: The only concern I have with you saying that it's a sideshow is that -- why are you relying upon an article or a study and you don't know how it was peer-reviewed?

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MS. O'DELL: Well --

THE COURT: And if you relied upon it and you didn't look into how it was peer-reviewed, then, I'm sorry, I think then whatever challenges are made to something that you relied upon, you had an obligation to be aware of what the criticisms, the professional criticisms, of the studies are because that way you would be able to make a determination as to whether or not it's something you will rely upon or something you will just simply reject.

MS. O'DELL: Yes, sir. In the scientific literature, what you have is the peer-reviewed, published paper. And the peer-reviewed comments are never available outside in the public.

So this is Dr. Saed. He submits this article to be published. There are these critical peer-reviewed comments. He gets those. Those are confidential. They are never put out in public, but because Dr. Saed is an expert in the multidistrict litigation, there was discovery on that. They were "attorneys' eyes only" documents for a long time, until just recently.

And now defendants are using them in depositions to cross-examine other experts who had no opportunity to see any of those. You know, an expert

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looks at what is in the peer-reviewed --

THE COURT: Why can't they just explain that?

Why can't -- I don't understand. You are almost telling me that we have to ignore the fact that there are other peer-reviewed professionals who have looked at this and been critical of it because those findings were not available.

And I would maybe be a little more sympathetic to your argument if your expert wasn't confronted with this at the deposition. So this is not like this is just happening totally out of the blue because your expert, even after the deposition, could have looked at this stuff and could have said, Hey, now that I have looked at this, I want to do an errata and I want to basically -- I want to modify my position in some way. And your expert didn't.

MS. O'DELL: That is fair, Your Honor. We did not do that.

THE COURT: So the objection is overruled.

MR. OLIVER: Okay. Your Honor, this is my final objection. There are several slides starting with Number 54. And also on 58. And they know better than I do where all this is. They say things like the US public health authorities do not support plaintiff's litigation claims. That's argumentative

	Page 463
1	and also false.
2	THE COURT: Yeah. I don't know anything about
3	false, but I do think it's too argumentative.
4	MR. OLIVER: Sure.
5	MS. BROWN: I can tone that down a little,
6	Judge.
7	MR. OLIVER: Same on 58.
8	MS. BROWN: Yeah. I understand. I understand.
9	MR. OLIVER: I mean, basically, I don't mind if
10	they are going to show the position
11	MS. BROWN: Yeah, I understand. I understand,
12	Your Honor.
13	MR. OLIVER: of the I mean, of the
14	agency, but I don't want them saying they rejected
15	any claims, because that's just not how
16	THE COURT: We're waiting for one more juror.
17	We're still waiting, so is there something else we
18	can take up?
19	MS. BROWN: Were there any outstanding
20	MS. STEMKOWSKI: deposition designations.
21	THE COURT: Other than deposition designations.
22	No, you can leave them here.
23	MS. STEMKOWSKI: May I approach and at least
24	give you the binders?
25	THE COURT: Yes.

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1	MR. REYES: Your Honor, may I be excused?
2	THE COURT: Yes, sir.
3	MR. OLIVER: Your Honor, as we organize
4	ourselves for opening, I was going to put a binder up
5	here and then move between here and the screen. Is
6	that
7	THE COURT: You're going to do what, sir?
8	MR. OLIVER: I was going to put my notes up
9	here, but I have got to get to the screen so I will
10	walk back and forth to the screen.
11	THE COURT: That's no problem.
12	MR. OLIVER: It's a touchscreen.
13	THE COURT: Okay. But can I tell you and
14	this is probably going to be a problem. Because we
15	have the jurors and we're going to have ten jurors
16	and they are going to be seated there. The juror who
17	is seated right there
18	MR. OLIVER: Right in front of the screen.
19	THE COURT: is not going to be able to it
20	is going to be uncomfortable. So what I normally ask
21	the lawyers to do is kind of move the screen down
22	towards us and then turn it at an angle.
23	MR. OLIVER: Can we do that, Gina?
24	THE CONCIERGE: Yes.
25	THE COURT: It doesn't have to be dramatic, but

Page 465 it just has to be so it is not all in their face. 1 2 Or you know what we can do? We'll just have no one sit there. We've got ten jurors. We'll just 3 have them fill up the ten seats and maybe that will 5 solve it. So maybe that will be okay. Let's --6 let's see how it works out. 7 MR. PENDELL: Your Honor, we can move it at any 8 time, so... 9 THE COURT: All right. There's no more motions 10 in limine? We're good? 11 MS. SCOTT: We still have motions in limine, 12 Your Honor. 13 THE COURT: Okay. 14 MS. SCOTT: One of our -- would you like us to 15 argue here or come approach? 16 THE COURT: It's up to you. You're fine right 17 there. MS. SCOTT: So, Your Honor, one of the motions 18 in limine that is we have is MIL 33. And it covers a 19 20 bunch of things. One thing that I wanted to talk 21 about, because it came up yesterday in voir dire --22 and I apologize. I'm a Texas lawyer so I don't say voir dire, I say voir dire. 23 24 But this issue of making charitable 25 contributions with any amounts that are received from

Page 466 1 damages. So it was a suggestion that came out in 2 voir dire when --THE COURT: Oh, when he said you can -- give it 3 to the plaintiff and the plaintiff can do whatever 5 they want. 6 MS. SCOTT: -- they can do whatever they want 7 with it, including donate it to charity. So we have 8 an MIL on that that precludes any sentiment, 9 reference, argument, as to what -- to using any 10 damages for charitable contributions, for setting up 11 any cancer foundation. You get the picture. 12 I agree. I don't know why -- why THE COURT: 13 is that relevant to anything? They give you -they're going to punish --14 MR. OLIVER: Is this your MIL on that? 15 16 MS. SCOTT: Yeah. 17 MR. OLIVER: That's fine. I don't really have a problem with that; however, I do want to make 18 19 something clear because this -- not her law firm, but 20 this other law firm, and I try these cases 21 frequently -- does punitive closings. You've 22 probably seen this. And they make a big deal, ladies 23 and gentlemen of the jury, this money is going to the 24 plaintiff. It is going to the plaintiff. 25 If that's going to be the closing, then I need

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to be prepared to let my client say, Well, in point of fact, I plan to give this to Sylvester Cancer Research Center. If they are telling me they're not going to do that in closing, then I think it's fine.

THE COURT: But I don't understand. The money is going to the plaintiff. And the plaintiff has 100 percent discretion on what to do with that money. I don't know why we are getting into this -- because, by the way, forgive me for saying it this way, but wouldn't everybody who is looking for a billion dollars -- I'm making a number up -- everybody who is looking for --

MR. OLIVER: Your lips to God's ears.

THE COURT: But everyone is looking for a billion dollars. Wouldn't they all say, But I want to let you know what I am going to do with this money. I am going to give \$100,000 to all the poor children who can't eat. I am going to give another \$250,000 to all of the orphan children, you know, all those little kids -- I mean...

MR. OLIVER: And that is why I am not really fighting it. I am agreeing to it. However, I do think there is a difference in me affirmatively introducing it, and then, in closing, the defense lawyers making argument.

Page 468 1 THE COURT: How about we do this: We -- nobody 2 will make any reference to it, and then if, during their argument, they do make reference to it, before 3 you get up in your rebuttal close, you say, Judge, 4 5 can we just have a brief moment, and then you explain 6 to me what you intend to do. 7 MR. OLIVER: Absolutely. THE COURT: And then I will rule. And it will 8 9 depend, in part, on how they argue. And then you 10 will tell me why you thought you have to do -- you 11 have to respond. 12 MR. OLIVER: That is perfect. That is perfect 13 with me. THE COURT: So motion granted, unless you, 14 15 quote/unquote, open the door. And what open the door 16 means, we don't know. We will have that conversation 17 at some point. MS. SCOTT: We will find out. 18 19 MR. OLIVER: And that may not be their plan at 20 all. 21 (Discussion off the record.) 22 They have sex cells attributed to MS. BROWN: 23 us in quotes, and that is not in the document. 24 THE COURT: Sex? 25 MR. OLIVER: That is a mistake. You will

Page 469 1 understand when you see the picture. 2 THE COURT: Oh. 3 MR. OLIVER: It is interesting, Judge. All right. Let's just take it out. 4 MS. BROWN: 5 THE COURT: Do you have something else, ma'am? 6 MS. SCOTT: Yes, Your Honor. We also have a 7 motion in limine to exclude references or evidence to 8 other litigation. This is another issue that came up 9 yesterday in the voir dire. 10 Obviously, there have -- there's been a lot of 11 talc litigation. A lot of the expert witnesses, as 12 Your Honor knows, are repeat players. And so the 13 fact they have given prior testimony is going to come in, but we don't believe there should be any specific 14 15 reference to the specific cases or the specific 16 details about that prior testimony. 17 THE COURT: I think it depends upon how you cross-examination them. I think you are the one who 18 19 has total control over that because if you -- there 20 are certain things that I have seen lawyers do and 21 you invite exactly what it is that they respond --22 that they give you. 23 So I think that depends upon -- more upon you. 24 And you can quide -- it is cross-examination, so you

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can fully guide the witness, and you can make sure, I

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don't want to make reference to any specific cases, but I do want to talk about some previous statements that you have made. Okay?

So depending upon how you ask the question -now, they can't gratuitously just go ahead and start
throwing out cases, and you should tell them that
they should refrain from doing that, again, unless
there is some specific reason as to, That is how I
got to respond to your question.

MR. OLIVER: Your Honor, we don't plan on doing that. I will say that the place that it is most likely to come up is with our last -- I hope it's going to be our last witness -- Mr. Diaz, who is going to talk about the relevant information about punitives and the bankruptcy. And he is going to make passing reference to it because it is a part of the transaction.

Other than that, if they don't open the door, the most that would come in would be, Hey, if they did open the door, there is a certain number of cases. I mean, in their opening, they say, There is all these millions of people who have used this product. At some point, it is fair, depending upon what they do, to say, Well, yeah, and a lot of them got cancer, and they brought these lawsuits.

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Page 471 THE COURT: Like I said, it depends upon how 1 2 they proceed. 3 MR. OLIVER: We're good to go. 4 MR. PENDELL: Your Honor, may I ask a 5 clarification question? 6 THE COURT: Sure. 7 MR. PENDELL: And I apologize. I know you only want to hear from one of us. I just want to get 8 9 clarification. 10 Here is my concern: For example, when I have a 11 witness on the stand, I want to be able to say to the 12 jury, Have you ever testified in a trial like this 13 before? Because my concern is if I don't do that, on cross-examination, they get up and say, Hey, you have 14 15 testified in 20 of these cases, haven't you? 16 THE COURT: Why can't you just ask, Have you 17 ever testified as an expert in a court of law? And the answer is yes. Why does it have to be, Have you 18 ever testified in a trial like this before? The 19 20 whole point is that you have testified as an expert 21 before? Before in Miami-Dade County? Yes. 22 Broward County? Yes. All across the United States? 23 Yes. Does it matter if it is in a case like this? 24 25 MR. PENDELL: Yes, if on cross-examination,

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they are going to go up and say, You have made \$20 million testifying in 17 talc trials, haven't you? And then it looks like I've hid that from the jury. So in that instance, that is why it matters. So if they are not going to do that, then I agree with you, we can do it that way.

THE COURT: I am not sure I agree with you.

But if they stand up and ask the question in the way that you just indicated, then I don't know why you think that somehow, that is suggesting that you are trying to hide that they had testified in talc.

But let me just ask: Do you plan on asking the question of the witness, You testified in 20 talc cases previously?

MS. BROWN: No, we do not, Your Honor.

MS. SCOTT: No, we do not, Your Honor.

THE COURT: So they are not asking that.

MR. PENDELL: No issue.

MS. SCOTT: The whole point of this is, really, we saw it yesterday in voir dire, where it was like, someone said if there were these other talc cases, then maybe I would think something differently. So we are just trying to hedge against that prejudice, Your Honor.

So obviously, we can speak in general terms

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Page 473 1 about prior expert testimony, but we don't want to go down that road that will lead to prejudice, as we 2 3 saw. 4 THE COURT: I agree with you, unless, of 5 course, the door is opened. MS. SCOTT: Unless the door is opened. 6 7 MR. OLIVER: We have several. 8 THE COURT: Well, we are still waiting for the 9 juror. 10 Are we still waiting, Rod? 11 THE CLERK: Yeah. We are still waiting for 12 that one juror. 13 THE COURT: Okay. And at some point -- just so that you know, he is now 40 minutes late. And we 14 15 have all done this. We have said, Oh, I am just ten 16 minutes away. That was 20 minutes ago. I am just 17 putting it out there for you all. At some point, we 18 got to just -- we have got to move on. 19 He is here? 20 THE CLERK: We are still waiting. 21 THE COURT: Yes, ma'am. 22 I am trying to kill some time here doing the 23 motions in limine, but at some point, I am going to 24 say we have to proceed. 25 Yes, ma'am.

Page 474 MS. SCOTT: Understood, Your Honor. 1 2 So we have a motion in limine. It is Number 21 to exclude references or evidence of any third-party 3 materials. And, specifically, there is an 5 unsolicited PowerPoint deck from a media company that J&J had used in the past that just -- again, 6 7 unsolicited marketing PowerPoint about marketing talc products to a specific demographic that Ms. Seskin 8 9 was not involved in. 10 THE COURT: I don't understand when you say 11 "unsolicited." You are saying somebody sent you a 12 proposal? 13 MS. SCOTT: It was a pitch deck. 14 THE COURT: Okay. So they, basically, pitched 15 a proposal, and you never used it? 16 MS. SCOTT: We never used it. It was internal. 17 MR. OLIVER: Your Honor, we are not using this. 18 This is marketing --19 THE COURT: So granted. 20 MR. OLIVER: We may use the document. We will 21 redact it. We are not talking to marketing people. 22 THE COURT: Ma'am. Granted. MS. SCOTT: I think that would also cover our 23 24 Motion in Limine Number 2 regarding reference or 25 argument that Johnson & Johnson improperly targeted

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consumers based upon demographic characteristics.

MR. OLIVER: No. Your Honor, we are absolutely going to talk about the fact that they targeted mothers and young women, and particularly in the time period that Marilyn Seskin was a young woman, and we are going to see that evidence, and it is indisputably relevant and indisputably a --

THE COURT: I'm sorry, is she a mother?

MR. OLIVER: No, she was not a mother, but their marketing campaign combined the concept of "this is safe enough for your baby," and in the same ads, it would say it is safe enough for your body. They did it all together, right? Some of them were just for babies; some of them were for mothers and babies.

THE COURT: Go ahead and finish your argument, ma'am.

MS. SCOTT: Your Honor, we believe that this targeting argument is irrelevant because there is no evidence that Ms. Seskin ever saw any J&J advertisements or relied on any advertisements. The only sworn testimony that we have from Ms. Seskin said that she saw advertisements, but not specific ones.

And there was a question on this fact

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questionnaire that specifically asked, Have you seen -- what are the specific marketing materials or advertisements that you have seen? And that space is left blank.

And so there is no evidence that she even saw the marketing materials that they intend to show. mean, some of these things are -- and we -- I think we talked about this in regards to Dr. Freidenfelds -- some of these things, like, way predate Ms. Seskin even being alive.

So there was, like, a 1917 World War I ad disclosed on Dr. Freidenfelds' opinions, or, like, a depression-era add. So these ads of targeting, they are just not relevant to this case, and they would be highly prejudicial.

MR. OLIVER: So those ads, first of all, are not really about targeting. Those are about establishing the brand and establishing reputational purity and safety and trust, and they do all that.

In talking about the targeting ads, with regard to targeting, Marilyn Seskin was given a sworn fact statement as she was dying and asked to identify ads without -- she didn't have the ads, right? I mean, she was in the hospital or at her house. She didn't have somebody showing her ads.

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So we are not going say she saw this ad. But what our experts are going to say, and what the jury can infer on its own, as well, is that, well, she was alive during this time period, she said she saw advertisements, and this is what the advertisements looked like, right?

THE COURT: At that time period.

MR. OLIVER: At that time, this is what they said to people and the purposes for which they marketed the product.

Some of those sexy ads are all about, like, well, you would use it as a feminine deodorant, right? That's what it's about, and that's how she used it. So it's directly relevant.

MS. SCOTT: Your Honor, I think this goes to the fraudulent misrepresentation claims which are totally based on these ads. There has to be a direct link between the alleged misrepresentations based on the ads, question if those are actionable, and the plaintiff actually seeing them so that she is harmed. There is no direct evidence making that link. And so these ads are completely --

THE COURT: These ads, is this argument going to the fraudulent misrepresentation that they said something in the ads that caused Ms. Seskin to

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actually use the product and the product caused injury?

MR. OLIVER: Your Honor, it would go to fraudulent misrepresentation, express warranty, the ads -- almost all of their ads say this product is pure and safe enough for you.

THE COURT: I'm not talking about that. talking about the part where you talk about how she used the -- why she used the product. Meaning, connecting the marketing to her use of the product. And what does --

MR. OLIVER: Your Honor, I'm not sure I understand your question. Yes, we believe that she trusted -- her husband testified that she trusted Johnson & Johnson and has specific examples of it. For example -- well, you'll hear the testimony. She trusted Johnson & Johnson. That's going to be the testimony.

We are going to offer these ads to show that they made these statements, that they are, in fact, not true. And the jury would have to infer, based on the years and based upon Bob's testimony and Dr. Seskin's sworn fact sheet, that she saw these representations.

THE COURT: Well, why do we need the jury to

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Page 479 1 interpret that? There has to be some evidence. 2 just simply saying --MR. OLIVER: There is evidence. 3 THE COURT: -- it seems like -- one minute. 4 5 You seem to be taking the position that because 6 they advertised at a time when she used the product 7 and she said she saw advertisements, that somehow 8 that equates to somebody saying that she had to have 9 seen the advertisements, that -- the specific 10 advertisements -- and I don't know which ones. Are 11 you going to show specific advertisements? 12 MR. OLIVER: We're going to show specific 13 advertisements. But you have nothing to show those 14 THE COURT: 15 were the ads that she actually saw. 16 MR. OLIVER: So, Your Honor, under the consumer 17 expectations test as articulated in Aubin, the Florida Supreme Court recognized that a manufacturer 18 19 sets its expectations with its representations to the 2.0 public. 2.1 In the following law that followed up from Aubin and some other law, I think it was Dagnin. 22 Ιt 23 went up to the Supreme Court, I think it was 24 Chadwick. The Florida Supreme Court and the lower 25 court which basically grappled with this nature of

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fraud and what you have to prove. And what they have said is if you can show that a plaintiff was, you know, alive and exposed to this advertising campaign, the jury can infer. And the jury instructions must say, I believe that the plaintiff relied on a statement or statements.

But the law is clear you don't have to prove which statement he or she relied on. Because when you're talking about something like tobacco --

THE COURT: But what I heard you say is just simply, she was alive and she was using the product at the time they were advertising. Then that would just make -- I'm thinking about in the context of cigarette smoking, and somebody comes in and they say, you know, well, okay, why would you start? By the way, you can bring in all these ads about why they started doing something --

Let me finish my statement.

You can bring in all of these ads about why somebody started to do something, and -- but that person never saw any of those ads. That doesn't make it relevant because they put out all of those ads. You have to at least link the ads to the person and the reason why she was using the product.

MR. OLIVER: That's right. Your Honor, first

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of all, we go back to her sworn statement, which I think they might have drafted. It's a plaintiff's fact sheet. They might have drafted it. They certainly had input into it, right? It comes from the MDO.

She filled it out and said, I saw Johnson & Johnson advertisements. Her husband said, Yes, I believe she saw these. I have this relationship with her. I lived with her for 20 years, and, you know, she watched television, she did all this. She trusted the Johnson & Johnson family.

THE COURT: He is going to say -- the husband is going to testify that Ms. Seskin actually saw specific advertisements?

MR. OLIVER: Not -- no. But we don't have to say that. The case law is very clear. We do not have to identify a specific statement or statements that she saw. You just have to --

THE COURT: But I'm sorry. Are you telling me she used this -- you allege that she used this product for 50 years.

MR. OLIVER: Fifty years, yes, ish.

THE COURT: Okay. So I'm trying to understand.

So you -- are you saying that you get to play

advertisements from, let's say, when she first

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started using the product? Then every decade you get to play -- I mean, because the husband, she and the husband didn't get married until 2006 or something like that? 2004. Thank you, Mr. Seskin.

They got married in 2004. So the only knowledge he would have about any advertisements would be in 2004. And even then, he would have to simply say, oh, it was a commercial that came on TV, or it was -- I mean, at least link it somehow. You can't just simply say, well, they advertised.

MR. OLIVER: That's not what we are saying,
Your Honor. We have a sworn statement from the
plaintiff that said she saw Johnson & Johnson
advertisements. Because of the circumstances of her
death and the nature of the fact sheet, she didn't
ever have an opportunity to say, I saw this or I saw
that. But I need to back up because this is
critical. Our defect claim, which is obviously
probably the most important claim in this case, given
that we have to prove the defect, relies on the
consumer expectations test. There is no doubt about
that under Florida law.

Under Florida law, in order to establish what consumer expectations are, the Florida Supreme Court has been clear, I get to show how they established

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expectations with their public statements. That's how consumers know what to expect.

If Johnson & Johnson never said a word about baby powder ever, I would have a problem. But they said a lot of words about baby powder. In order to say they failed the consumer expectations test, that's relevant evidence to that defect. So that is part one.

THE COURT: So there is a difference between you talking about whether or not they failed the consumer expectation test and somehow you allowing your people to come in and testify that somehow she relied upon these statements that were being made.

MR. OLIVER: I'm not going to say -- no. I'm not having -- I have never personally believed that experts should say somebody relied on something directly because that's a very hard thing for any expert to say unless they are your psychiatrist. So I'm not going to have an expert come in and say, she relied on this.

I think reliance is something that a jury infers from the circumstantial evidence that is offered. So if Your Honor thinks that an expert is going to come in and say she relied on this ad, that's not what they're going to say.

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THE COURT: Well, are they going to link? Because you have referenced to --

MR. OLIVER: Yes.

THE COURT -- your fraud count.

MR. OLIVER: Yes.

THE COURT: My question is, and this is the concern I am having, is I don't know how they link it. I think there's a problem with this -- there is something missing in this link. So I think you all need to brief this.

MR. OLIVER: What is the missing link? I don't understand.

THE COURT: Because you're -- they're just coming in and they're saying, Well, because they advertised, and no one disputes that Johnson & Johnson advertised, and she was using the product, and she said -- the husband says that, yes, she saw -- she said in her statement that, yeah, I saw advertisements, then you get to then put into the record how Johnson & Johnson was marketing and advertising their product. And, by the way, for what period of time? For the entire 50 years?

But you can't even say, for example, when I originally started using the baby powder, I remember seeing ads that showed the mother with their baby and

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them saying that it was fresh and it was clean. mean, you have to -- or at least put it into a decade. But you are not putting it even into a decade.

You're just basically saying she used the product for 50 years. And then you think that that gives you carte blanches to bring in all the advertisement that they have used for 50 years? Ι have a problem with that.

MR. OLIVER: Okay. Your Honor, I understand your position, but I really think that if these are excluded it is reversible error. Because I have to be able to offer you my case.

THE COURT: Let me tell you all something. am not afraid to have my name in print. So when you all use that phrase "reversible error," I do the best I can with what you all give me. I paused. And I said maybe you need to brief it. That's my way of saying, you may need to give me some more education. Help me understand why I should let it in. obviously struggling with it.

But you all -- every time you all use that word, by the way, I always sit back and I always say, it never scares me. I have been reversed. Not because I did something intentionally. I thought

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this was the law. I did the best I could do. If the reviewing court, there are wiser people up there, if they think I made a mistake, I learn from it and I move on. But you have to educate me, help me make the right decision.

MR. OLIVER: So, Your Honor, I need to understand, because, quite frankly, there was a lot going on. And Ms. Scott was talking to you while other people were talking to me, and I didn't hear the first part of her motion.

What I want to understand is -- I know about the briefing. I got that, and we will brief whatever needs to be briefed. But I have these ads in my opening. I brought them to Ms. Brown. She didn't object.

THE COURT: And I'm not disturbing your opening. I have no idea what is going. This is a motion in limine not raised in the opening. So -- about the opening. So I'm not changing your opening.

MR. OLIVER: Okay.

THE COURT: But, again, I don't know what you're going to say during the opening.

MR. OLIVER: I don't know what they're going to -- if they're not trying to take it out of the opening, I don't know what it is they are getting at.

Page 487 1 These are their statements. I mean, it's not --2 Well, go ahead. Tell him. Now, they're going 3 to make an objection about my opening. Well, I mean, in light --4 MS. BROWN: MR. OLIVER: They didn't make. 5 MS. BROWN: -- and the Court's ruling, they 6 7 have in here "baby powder is sexy." 8 THE COURT: But you didn't object. I told you 9 all, you all have to look at each other's slides --10 MS. BROWN: That's fine. 11 THE COURT: -- and we sat here at the beginning 12 of this and you didn't object. 13 MS. BROWN: Understood. THE COURT: Had the juror not been late, 14 15 counsel would have done his presentation based upon 16 my ruling upon the objections that you made. Now, 17 we're having this conversation, and now you're 18 saying, Well, Judge Thomas, in light of that, now we 19 want to object. 20 MS. BROWN: Well, what I'm saying, Judge, and I 21 understand he sort of opens on this at his peril. We 22 had full intention of getting this motion before you, 23 and when he tries to use it with a witness, then, hold on, she never saw that ad. So I didn't object 24 25 to the opening because these are our ads.

Page 488 1 THE COURT: And I'm not precluding you from 2 doing that, by the way. Okay. I understand. 3 MS. BROWN: But I'm not going to require you to 4 THE COURT: 5 change your opening. But, of course, you do use your 6 opening statement to your own peril because I don't 7 ultimately know -- because when you give me that 8 memorandum, and you help to educate me a little bit, 9 if I don't see it the way you want me to see it, 10 then, unfortunately, you are stuck. 11 MR. OLIVER: Your Honor, one thing that I want 12 clarification on, because I am not sure what Your 13 Honor is asking, you keep saying, We just want to say she used baby powder and, therefore, she must have 14 seen the ads. 15 16 She said in a sworn statement she saw Johnson & 17 Johnson advertisements. And the law says she doesn't --18 19 She used the product for 50 years. THE COURT: 20 MR. OLIVER: True. 21 THE COURT: So the question is: Did she see 22 Johnson & Johnson advertisements in 1960? Is that 23 50 years? In 1980? In 1990? Was it in 2000? Were 24 the ads the same? What were they -- I mean --

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MR. OLIVER: They were different. We will

offer them into evidence and show the difference.

THE COURT: But that is the whole point. The point is that if she didn't see advertisements

50 years ago, how old was she? When she first started using it, with 50 years of using it --

MR. OLIVER: She had it used on her as a baby. She began using it, probably, based on Bob's testimony and her fact sheet, when she became of sexual maturity. So, you know --

THE COURT: When was that? How old was she when that happened?

MR. OLIVER: So 1949, it would be '59, early '60s.

THE COURT: So the early '60s. Did she see advertisements back then?

MR. OLIVER: I don't think anybody can tell you that. She said she saw them, okay?

THE COURT: And --

MR. OLIVER: I don't think the law requires that either.

THE COURT: And, again, we can sit here and we can continue to have this conversation, and you are not going to persuade me to change my thoughts unless you educate me and give me some case law that maybe I am wrong in the way I am thinking about it. And how

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many judges pause and say, Educate me. Help me get to where you want me to be?

You standing up there and getting frustrated because I don't seem to see it the way you want me to see it, that is not productive. All it is, is you repeating it and saying, Why are you so thick? Why can't you get this? And I am saying to you, I am being thick because I am not seeing it the way you want me to see it. Educate me.

And if you educate me and I see it your way, I will overrule it. And if you don't, then that is the ruling.

MR. OLIVER: Okay.

THE COURT: And then whatever the reviewing court does, if you get an adverse verdict, then if they reverse it, they argued it, and then you would have to try it all over again. I can't do anything more than that, and I don't think anybody could ask me to do anything more than that.

So I gave you an invitation. You either take me up on the invitation, or you leave me to my own devices, and I make the best decision I can make based upon what you have given me.

MR. OLIVER: We will absolutely take care of that, Judge.

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1	THE COURT: The jurors are here. Jurors coming
2	in.
3	(Jurors entered the courtroom.)
4	THE COURT: Please, ladies and gentlemen, you
5	are the jurors that have been selected and sworn to
6	try this case. As we have indicated to you, we are
7	about to do opening statements, but there are a
8	couple of things that I have to explain to you before
9	opening statements begin.
10	First, I have to ask, did any of you do any
11	independent research about this case? Anybody do any
12	independent research about the case? You've got to,
13	to answer me. You've got to tell me.
14	THE JURORS: No.
15	THE COURT: Okay. Did any of you speak to
16	anyone about the case?
17	THE JURORS: No.
18	JUROR YESILAN: My husband.
19	THE COURT: You spoke to your husband about the
20	case?
21	JUROR YESILAN: Yes.
22	THE COURT: Ladies and gentlemen, can you all
23	just step into the jury room for just a brief moment
24	for me, please?
25	(Jurors exited the courtroom.)

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THE COURT: Ma'am, can you just step out here for a brief moment for me, please.

(Juror Yesilan exited the courtroom.)

THE COURT: Rod, take her away from the doors.

I am loud. My voice carries.

Okay. I think she did that on purpose. I don't know what she is about to say, but I wanted to know -- now that she is a juror, I try not to have the lawyers ask the questions, but I want to give you all an opportunity, if you think there is a question that I should ask of her.

I am, obviously, going to ask her, What was the conversation that you had with your husband? Okay? What did you say to him? What did he say to you? Okay? Depending upon that response.

But regardless of what she says -- she is an alternate juror, right?

MS. BROWN: Yes.

MR. OLIVER: She is.

THE COURT: Regardless of what she says, she will stay here for the entire period of this trial.

Okay? And so whether she actually sits and deliberates or not, she will sit here, and I will make her stay. But I don't want you -- when I do that, I wanted to tell you all why I was doing it.

Page 493 1 don't want you all panicking because, you know, you 2 are concerned that she is on your panel. She may be stricken, but I am not excusing her 3 because I think she did it on purpose, if she --4 5 because I clearly told them not to talk to anybody about the case. 6 7 All right. Rod, can you bring her back in for me, please? 8 9 (Juror Yesilan entered the courtroom.) 10 THE COURT: All right, ma'am, you can go back 11 over to your seat. 12 All right, ma'am. You indicated, when the 13 Court asked whether or not you had spoken to anybody 14 about the case, and you said you had spoken to your 15 husband. What did you say to your husband? 16 JUROR YESILAN: About what happened yesterday. 17 THE COURT: Can you be more specific? 18 I spoke about it in the case. JUROR YESILAN: 19 THE COURT: Give me an example. 2.0 JUROR YESILAN: Sorry, I cannot explain much 21 because my English is not enough to explain. 22 understand, but I cannot talk. I can't. 23 THE COURT: You cannot articulate what you said 24 to your husband? JUROR YESILAN: How I can explain? I said 25

Page 494 1 whatever happened. Whoever talks, that is what I 2 speak about. THE COURT: You said specific things about the 3 case, what you understood about the case? 5 JUROR YESILAN: Yeah, because of the, you know, the talc, the powder. That is why I talked, Johnson 6 7 & Johnson. THE COURT: What did he say to you? 8 9 JUROR YESILAN: He didn't say anything. He 10 just listened because he doesn't know anything about 11 it. 12 THE COURT: I need to reinforce to you again, 13 you are not to speak to anybody about this case, including your fellow jurors. It is improper. You 14 15 are not allowed to have a conversation with the 16 jurors or with anybody about this case until the very end of the trial when you are in the jury room. 17 JUROR YESILAN: Okay, but he is my husband. 18 19 have to talk with somebody. I have to explain my 20 things. I cannot let this -- and let it stay like 21 that. I cannot. It has to be somebody. 22 THE COURT: Ma'am, you are not allowed to talk to your husband --23 24 JUROR YESILAN: I cannot promise, sir. I am 25 sorry.

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1	THE COURT: about this case.
2	JUROR YESILAN: I cannot promise.
3	THE COURT: Well, ma'am, here is the problem,
4	is that you have to follow the orders of this Court.
5	And I pray, I am begging you to please
6	JUROR YESILAN: You don't have to beg me. You
7	are not why are you begging me?
8	THE COURT: Because you seem to have some
9	apprehension. You seem to have some concern.
10	JUROR YESILAN: Yes, I am.
11	THE COURT: Let me finish my sentence.
12	JUROR YESILAN: I cannot understand what they
13	say. I have to ask somebody what he says. I don't
14	know. The English is not my first language. I speak
15	Armenian, I speak Turkish, I speak a little bit of
16	French, but not fluently English.
17	THE COURT: I am sitting up here listening to
18	you, and you are communicating well.
19	JUROR YESILAN: Well, but
20	THE COURT: You answered the question.
21	JUROR YESILAN: I don't understand. I am
22	speaking only the basics.
23	THE COURT: Ma'am, here is the bottom line:
24	You are here for the two to three weeks that you have
25	been selected. There is nothing you can say. There

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1	is nothing you can do.
2	JUROR YESILAN: If I get sick, what you going
3	to do about it?
4	THE COURT: There is nothing you can say, there
5	is nothing you can do that is going to change that.
6	And if you violate my order again, then,
7	unfortunately, we are going to have to have another
8	conversation, and I don't want to have that
9	conversation with you.
10	JUROR YESILAN: I am sorry. I cannot promise.
11	THE COURT: Jurors coming in.
12	JUROR YESILAN: You think I can't talk anybody?
13	Everybody can talk.
14	THE COURT: Nobody can.
15	JUROR YESILAN: That is what you're thinking.
16	THE COURT: That is what I am thinking?
17	JUROR YESILAN: Yes.
18	THE COURT: And you should let me know if
19	somebody attempts to talk to you about the case.
20	JUROR YESILAN: That is not my problem.
21	THE COURT: Ma'am, I am trying. I am really
22	trying and you are testing me.
23	Jury is coming in.
24	JUROR YESILAN: Because you don't listen to me
25	yesterday when I talked to you.

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(Jurors entered the courtroom.)

THE COURT: For the record, all of our jurors are present. All parties are present.

I need you to do a couple things for me. The first thing I need you to do for me -- everybody can be seated -- is I need you to turn your phones on silent or turn them off. If you could do that for me, please. That is just so that the lawyers are not interrupted during their opening, and then you all will remember to turn it off.

The next thing, and I need to make sure you all strictly comply with what I am about to say to you, you are not permitted to have any conversations with anyone about this case. This includes your mother, your father, your husband, your children, nobody.

Okay? And that includes each other.

If a juror approaches you and attempts to have a conversation with you about this case, if the juror leans over and says, What did they say -- okay? -- you don't answer that question. Okay?

And if a juror contacts you and attempts to have a conversation with you about this case, you must immediately bring that to my attention. Write a note. You are going to have a notepad. You write a note to me and you tell me, This juror is attempting

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to talk about the case. You have to let me know that. Okay?

When we take breaks from time to time, you are not permitted to talk about this case. When I send you in the jury room, you are not permitted to talk about this case. I don't know how else I can say it.

It is so important that you not talk about this case until the very end, when all of you are present in the jury room and you have heard all the evidence and I have given you instructions on the law. That is the only time you are able to talk about the case.

When a witness is on the witness stand, if you like what the witness is saying, you don't like what the witness is saying, you can't turn to the other juror and say, I don't like this person. Okay?

That's talking about the case. Okay. You can't give anybody else your impressions of the testimony of any of the witnesses here in court. Okay.

The second thing is that in about two minutes the lawyers are going to stand up and give you their opening statements. Remember, I told you what the lawyers say is not evidence. Evidence is what you hear from the witnesses from the witness stand, the exhibits that are admitted into evidence and any facts that I tell you, you must accept as true.

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The lawyer speak is not evidence. But we are going to ask you to pay very close attention to the opening statements of the lawyers because it's a road map, it's what they believe the witnesses are going to say when they actually come into court and testify. Okay.

Immediately after the opening statements, we will then have the presentation of witnesses. plaintiff will call their witnesses. The defense has an opportunity to cross-examine those witnesses. after the lawyers have asked all of their questions, you will have an opportunity to ask the witness a question. Okay. But your questions are not verbal. You will have a notepad and a pen. You have to write your question on a sheet of paper. You pass the paper to me. I then review it with the lawyers, and I will then make a decision as to whether or not your question can be answered.

I will tell you now, not all of your questions are going to get answered. Okay. It's not because it's a bad question. We are governed by rules of procedure and evidence, and so we are just -- you may not be trained in that, and so not all of the questions that you ask can be answered.

The fact that I don't answer a question that

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you submit, that should not discourage you from continuing to ask questions if you should have other questions. Okay.

Also, you are allowed to take notes. You will have a notepad and you can take notes. Please don't become so consumed with taking notes that you are not paying attention to the testimony as it's coming in.

Also, I want you to remember -- and I will tell you this at the end of the case -- that the fact that you wrote something down on your notepad, if you remember it different, okay, it's what you remember, not what you wrote on the notepad. Okay? So don't say that must be it because I wrote it down there. But I remember it in a different way. We want you to focus on your independent and collective recollection as compared to just simply locking it in because you wrote it down on the notepad.

We have to take breaks periodically. And when we do, you are not permitted to discuss the case. We ask that you use the bathroom -- we're going to try to have you go into the jury room, there's a bathroom back there, there's water back there. We are going to ask that you use that bathroom so that the lawyers can use the bathroom up here on this floor. Because, again, we want to limit the exposure that you have to

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Page 501 1 them so there is nothing inappropriate -- or 2 potentially inappropriate should occur. There are some additional instructions that I 3 am sure I am going to need to give you, but I want to 5 get to opening statements of counsel. Counsel, would you like to give an opening 6 7 statement. 8 MR. OLIVER: Yes, Your Honor. 9 THE COURT: Yes, Mr. Neuman? 10 JUROR NEUMAN: Can we get a notepad now? 11 THE COURT: No, because what the lawyer's say 12 is not evidence. So I will give you the notepad as 13 soon as the opening statements are over. Okay? 14 JUROR NEUMAN: Thank you. 15 THE COURT: Thank you, Mr. Neuman. 16 MR. OLIVER: I would be thrilled to give my 17 opening statement. Good morning, ladies and gentlemen of the jury. 18 19 As you know by now, my name is Lance Oliver and I'm with the Motley Rice law firm. I now finally have 20 21 the pleasure of introducing you to my client, Bob 22 Sugarman. 23 Bob, can you stand up and wave? 24 I also have the pleasure of introducing you to 25 my team who will be trying my case with me.

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here we have Gina Veldman, she's my favorite person to try cases with. She keeps all of our audio-visuals going and she is absolutely essential.

My trial partner here is Ms. Laura Stemkowski. She is the second chair in this case. You're going to hear from here.

I have Ms. Lee O'Dell from the Beasley Allen law firm, and my partner Michael Pendell, who you will also hear from.

And you're going to hear from the four of us, but there are a lot of other people working on this case, other members of my team, and this is a team effort. And I want to thank them first.

So we are here on behalf of Bob. But Bob is here as a personal representative here on behalf of his dead wife, Marilyn Seskin. Bob is an attorney. He represents local health and benefit welfare firms in this area and across the State of Florida.

Before she passed away, his wife, Marilyn
Seskin, was an anesthesiologist. And you will hear
evidence in this courtroom that for pretty much the
entirety of her life Marilyn Seskin used Johnson's
talc-based baby powder as a deodorant, as
antiperspirant. She put it on her body. She put it
in underwear. And put it on her genitalia. She also

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put it on her diaphragm, which was her chosen form of birth control. So before she would have sexual intercourse, the diaphragm would have baby powder on it and she would insert it into her vagina.

In 2016, you are going to hear evidence that Marilyn Seskin was diagnosed with a form of ovarian cancer called primary peritoneal carcinoma. And it was of a cell type of high-grade serous cell cancer. Right now, that doesn't mean anything to you, but eventually it will when you hear the expert testimony.

From 2016 to 2019, you are going to hear that Marilyn underwent four surgeries. She had five rounds of chemotherapy. And you are going to hear that Bob was with her every step of the way. And in 2019, you are going to hear that, with Bob by her side, she lost that battle with cancer.

So this is a case about Marilyn Seskin's life, but it's also a case about a product and a company that makes that product. The product is Johnson's talc-based baby powder. Johnson's talc-based baby powder is a cosmetic. It is not a pharmaceutical. There will be no evidence in this case that Johnson's baby powder is medically necessary. There will be no evidence in this case that Johnson's baby powder

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saves lives. In fact, it does not.

Because of this, Johnson & Johnson told its customers for the entire existence of the company since Johnson's baby powder was on the market, that Johnson's baby powder was best for baby, best for They told all of their customers and the whole world that it was good enough for the entire world.

Why does that matter? I'm about to show you a series of advertisements that relate to what messages Johnson & Johnson put out there throughout Marilyn Seskin's life, and before and after. Because it set the expectations in the market for what consumers could expect of Johnson's baby powder. They made those statements. They set those expectations. you're going to hear the consumers like Marilyn Seskin trusted them and believed them.

Johnson & Johnson understood that. On the screen you see a document that we hope to introduce into evidence, which is a marketing presentation from the '90s from the Johnson & Johnson companies.

Johnson & Johnson recognized internally that this relationship of trust that it had developed with women and with mothers in particular was something monetarily valuable to them. No matter how much money the product actually made, that reputation was

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critical to their company as a whole.

This document shows what Johnson & Johnson believed "trust" meant. Trust in healthcare means a product that will work without any unexpected adverse physical or emotional effects.

So you probably have been asking yourself for a day now, how did one of the most trusted baby product manufacturers in the world end up in a courtroom as a defendant in a lawsuit? Here we have our road to the courthouse.

In a sentence, Johnson & Johnson ended up in this courtroom because that trust that they engendered with their customers like Marilyn Seskin, they exploited it over and over again for money.

So at the end of this trial, you're going to have a job. And one of those jobs is going to be to determine, did the product, Johnson's baby powder, cause Marilyn Seskin's cancer and death? To answer that question, you are obviously going to have to learn a lot about Johnson's baby powder, the product.

The first thing that you might want to know about that is what is in Johnson's baby powder. We are going to bring witnesses who will talk about this. We are going to bring some of the company's own documents that talk about this. And here are the

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things that you might not have known. You probably walked in knowing what Johnson's baby powder is. But did you know what is in it?

So, first of all, Johnson's baby powder is made -- there are two versions. There is a cornstarch version that we allege in this case was perfectly safe and Johnson & Johnson had it for many years. You can buy that. The one we are complaining about is talc-based baby powder. Talc is a rock.

It's a mineral. I didn't know that before I started working on these cases. It is mined in the ground just like many other minerals. If you grind talc up, it can come in a plate-like shape, like a platy -- they call it platy talc in the documents. But it can also come in a needle-like shape, and that is called fibrous talc.

Needle-like shapes are important because there is another mineral that is often a contaminant of talc. That is asbestos. The experts will tell you that asbestos also comes in a needle-like shape, and there is a the problem with the mineral asbestos. It is a known cancer-causing agent. And talc also comes in the needle-like shape. But talc and asbestos grow together. You're going to hear testimony in this case, you are going to see documents, that when talc

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and asbestos grow together in the mines, you cannot effectively completely separate those things. And we claim that much of that asbestos, or some of that asbestos ended up in Johnson's baby powder.

On the right side of the screen we have our definitions. Platy talc. I talk about that. The International Association for the Research on Cancer, we will show you evidence, has classified platy talc to be a possible carcinogen. The International Research on Cancer has classified fibrous talc as inflammatory, just like platy talc, but they have classified it as a Group 1 carcinogen. The International Research on Cancer has established asbestos as a Group 1 known carcinogen.

So what does this list of ingredients have to do with Marilyn Seskin?

Well, this is what it has to do with Marilyn Seskin. You will hear evidence in this trial from doctors that when talc is applied to underwear or on the genitalia, it can migrate through the birth canal up through the fallopian tubes and it deposits itself on the ovaries and in the peritoneum. I am going to do my best not to use thousand-dollars words, but that is one that is important.

And I want to show you what I mean. The

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peritoneum is one of the places that Marilyn Seskin had her cancer. Well, I can't draw on this. But if I could draw on it, I would draw a big red circle around here. And that is because the peritoneum is essentially -- they call it the peritoneal cavity. It is the body cavity that houses our organs and houses the female reproductive organs in particular.

You're going to see that this is exactly what happened to Marilyn Seskin, and in 2016 she was diagnosed with primary peritoneal cancer. It was on her ovaries, it was in that body cavity in the peritoneum and her death certificate says fallopian tube cancer. These are interchangeable terms.

So this, as you have obviously guessed as Judge Thomas told you, is my opening statement. It is my time to tell you what I think the evidence will show. Before I jump right into that evidence, I have what we call in the legal business a housekeeping matter, and it just means it is something that is not really directly part of the story, but you need to know up front.

There are two defendants in this case. The first defendant, Johnson & Johnson, you have heard of. The second defendant is a company called LTL Management LLC. You have probably never heard of LTL

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Management LLC. LTL Management LLC did not exist until October 2021.

And you will learn that during the time we are complaining about, Johnson's baby powder was marketed and sold first by the Johnson & Johnson companies, then later, they transferred that to one of their wholly-owned subsidiaries called Johnson & Johnson Consumer, Incorporated.

When LTL came into existence, Johnson & Johnson consumer ceased to exist. They put all of the talc-related liabilities into this company, LTL. does not make any products. It does not do -- sells nothing. But it is in this courtroom because, by matter of law, it has accepted the liabilities for cases like this that flowed from that former company, Johnson & Johnson.

I am only telling you that because you need to know up front. I am simply going to refer to them jointly as the Johnson & Johnson companies.

So let's get into the evidence. On the screen, I have an advertisement from -- I believe, if we look up here, it is from the -- this one is from 1920, from the Ladies' Home Journal. And the reason I am showing you -- I am not saying that Marilyn Seskin saw this. She was not alive. The reason I am

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showing you this is because I am trying to show you how they started marketing that product.

Johnson & Johnson baby powder has been on the market since 1894, and from the very beginning, they told their customers two things about the product always. They said it is pure and it is safe. Early on, they would make appeals in advertisements to medical professionals. You'll see nurses and doctors on this. And they said things like this: They said it has the highest recognized purity. It is best for baby and best for you.

That "best for you" part is the most important part here, because from the very beginning, Johnson & Johnson, they set the expectation that it was safe enough for your baby, but they also set the expectation that it was good enough for you to use on your body.

One of our experts will tell you that these advertisements frequently use the word "toilet powder." And back in that time, they were more modest. They didn't have TikTok and all that stuff, so they didn't say everything that was on their mind.

They called something a toilet powder if they knew you were going to use it as, like, a feminine deodorant or something like that. It was a polite

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way of saying, back then, that you can put it on your body.

This is an advertisement from the 1930s. Why is this advertisement important? In this advertisement, Johnson & Johnson actually compares its Johnson's baby powder to other manufacturers' products. And in the 1930s, Johnson & Johnson says, "The inferior talc used in some baby powders contain sharp, needle-like particles. You wouldn't want them next to your baby's skin."

That is important because those needle-like particles that we talked about, we believe we are going to show evidence that they actually were in Johnson baby powder, and that for decades, Johnson & Johnson knew that.

This is another advertisement from the early ads, and, again, it shows that Johnson & Johnson marketed it for women and, ultimately, for men, to use from face to feet. They set the expectation that it was okay to use this powder and safe in this way.

Now, you may have come into this courtroom knowing a little bit about that, that Johnson had marketed its product as safe and pure. What you may not have realized is that in the mid-'60s, when Marilyn Seskin was coming of age -- she was born in

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1949; so in 1966, she was 17 years old -- Johnson & Johnson started marketing to adults. That's a euphemistic term. They actually started marketing to teenagers.

And they didn't just tell young mothers it was okay for their baby. They led young women to believe that this was sort of an acceptable deodorant and acceptable form of perfume to mask natural body odors that they shouldn't have been ashamed of.

But these ads are examples. These ads are from the '70s when Marilyn was in her early 20s. "You stop being sexy when you stop trying. If you would rather be fresh and natural, you are outdated."

So from the beginning, they said it was fresh. They said it was pure and natural and safe, and then in the '70s and '60s, they started marketing more for teenagers and adults. They kept the theme of purity, but they also said, Hey, this is a way to be attractive to the opposite sex or whoever you are attracted to.

Now, we are going to bring you a PhD witness who will explain all of this, and not surprisingly, Johnson & Johnson's advertising worked. This document shows that in 1966, when Johnson's powder began advertising to adults, sales increased

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tremendously.

So here is where they started that. what their competitors are doing. And sales of Johnson's baby powder went way up.

There is a great quote, and I may have to read I hope I can remember it. Actually, I am going to read this quote because I think it is really important. It is a quote about knowledge. You have all heard the quote "knowledge is power."

Here is the quote that I think says it even "There is no wealth like knowledge. is no poverty like ignorance."

And this is a fancy way of saying that when you have knowledge about something, it is a power, and when you don't share that knowledge with something, you are taking away their choice to use that knowledge.

And the evidence in this courtroom is going to show that is what Johnson & Johnson did for Marilyn Seskin and for all of its female customers because it didn't share the knowledge it had about the dangers of its product, and if it had shared that knowledge, their lives could have turned out differently.

So what did Johnson & Johnson conceal, at least from our perspective? This is a 1971 memo.

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J&J telegram. It was not a public document. In the early 1970s, there was a cancer research institute in Great Britain. It was called the Tenovus Institute, and they were doing research on various kinds of cancer. One was ovarian cancer.

So in 1971, the Tenovus Institute looked at slides of women's tissue who had ovarian cancer and found talcum powder particles, and that became big news. So this man from public relations at Johnson & Johnson is telegraphing somebody else, or giving a telegram, saying, Look, these guys have done this research, and there is a cancer peril in talc.

Why does that matter at the time? It matters because the Tenovus Research Institute scientists were concerned about the similarities between talc and asbestos, which was a known cancer agent.

So you are not going to see any evidence at this time that alarm bells went off in Johnson & Johnson and that they went out and warned people. In fact, exactly the opposite. You are going to see no evidence that they made any effort to warn their customers of this.

So this story goes on. It is very interesting.

Johnson & Johnson, the evidence will show, wanted a
second opinion. They began to follow this issue.

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They took the very same ovarian cancer tissue, and they sent it to Mount Sinai in New York, which you may have heard of. It is a very respected hospital. Good cancer institute.

At that time in 1971, there was a scientist doing research on asbestos. And so they sent it to Mount Sinai, and they also sent some samples of their baby powder, and they said, Will you look at this and give us a second opinion?

So that scientist at Mount Sinai, first of all, he found talc particles in those tissue samples.

But, second of all, he said, We also got a few surprises, and that we observed chrysotile asbestos to be present in the tissue as well. He also found fibrous talcs in Johnson's baby powder and trace amounts of chrysotile asbestos in Johnson's baby powder. That is a sample that Johnson & Johnson sent to them.

Again, when this happened, no warning bells went off. Johnson & Johnson did not make an effort at that time to warn its female customers.

So the scientist at the Tenovus Institute might have been surprised. But the evidence is going to show that Johnson & Johnson was not surprised at all because Johnson & Johnson had known this for quite

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some time.

You will, for example, see some documents from their own mining records showing in the 1950s that it was reported to them multiple times that there were certain amounts of asbestos in their talc mines.

This is a memo that is an example of that. It is not about the -- it is not the mine report itself. It is a memo from 1969. It was a formerly confidential Johnson & Johnson document. They produced it in this litigation.

Johnson & Johnson executives say it is normal to find different levels of tremolite. Our experts will tell you that tremolite is one form of asbestos in many US talcs. Tremolite has been banned because it has needle-type crystals. Later in the memo, he says some of that matches asbestos.

So the memo right next to it is another example. Johnson & Johnson company, Johnson & Johnson executives say -- they talk about the mines in this memo, and you will see the whole memo. But they also talk about their baby powder, and they say, "Our baby powder contains talc fragments classifiable as fiber." That is that fibrous talc that we talked about.

"Occasionally, sub-trace quantities of

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tremolite or actinolite are identifiable under an optical microscope, and these might be classified as asbestos fiber."

No evidence that warning bells went off at Johnson. No evidence that they told anybody about this publicly. In fact, they are going to say they didn't.

Quite the opposite. What they did, the evidence will show, is they developed a three-pronged attack to protect their marketing and their product. The first one was deny, deny, deny.

So on the screen, I have a New York Times article, and the New York Times article is about a study that came out in 1982. We are going to give you the actual study. We are going to introduce the actual study.

The reason that I use the New York Times article is because it has statements from Johnson & Johnson that show their position.

So in 1982, there was a graduate student at

Harvard. And I think -- I am not sure if he had his

PhD at that time, but he was a young researcher. And

he did what's called an epidemiological study. An

epidemiological study is where you study populations

of people and see if a substance -- it could be

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anything; it could be benzene, it could be cigarettes, whatever -- causes cancer.

It is -- you will hear from the experts, epidemiology is one of the basic ways in science that we know how something leads to a different disease state.

So this young researcher, who became one of the preeminent researchers on this particular area, this is his first paper on this. And he does this study and shows a statistically significant association between genital talcum powder use and ovarian cancer. And he publishes that, and he gives interviews about it. Here it is in the New York Times.

Johnson & Johnson responds by criticizing the study as inconclusive, and then they say, We can confirm that our talc doesn't contain any asbestos.

And you're going to see multiple statements

like that over -- like that from them over and over

again. And they are even going to say that. Johnson

& Johnson is going to say the same thing in this

courtroom.

But that's not all that happened with Dr. Cramer. He went on to do other research. But Johnson & Johnson actually at that time sent one of their executives to meet him at Harvard. And you're

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going to hear testimony that he told them to warn their customers about this. That's not what they did. They tried to convince, and they did so successfully for a while, this young graduate student not to give public interviews about the subject.

So that's the first prong of their attack. Deny, deny, deny.

The second prong of their attack was to create doubt about this science as it emerged. Now, if you can see, I jumped from early '80s to 1997. You're going to see various documents over various decades. Obviously, we don't have time to look at the whole historical record, but our experts put it in chronological order from you.

This is a letter from one of Johnson & Johnson consultants. They paid him. He was hired by them. His name is Dr. Alfred Wehner and this is from 1997. Dr. Wehner, the evidence will show, is writing to Johnson & Johnson to talk about some statements it was helping the Cosmetic Toiletries and Fragrances Association put out. Johnson & Johnson worked through a Washington-based trade association to put out some of these statements. And you are going to hear claims that there were other industry participants involved in that as well.

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So they would get together, Johnson & Johnson would say something, the CTFA is what we call it, they would say something else. And they were trying to create doubt. So in this private letter, Dr. Wehner, who they hired, called them out on that.

So the CTFA was saying human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk.

What does Dr. Wehner tell Johnson & Johnson about that statement? He says that statement is outright false. They're making false statements and their own consultant told them.

Another statement that the CTFA was making was the workshop concluded that although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association.

So the workshop is a reference to a group that the FDA, the Food and Drug Administration, got together to study this issue. And you will hear some more about that.

But basically the CTFA said, hey, there are all

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these studies now. Remember, we are in 1982. That was the first one. At this point there are more studies, and they keep showing a statistically significant connection between these things.

So the CTFA had attacked these and said there is no real association. Dr. Wehner says this statement is also inaccurate, to phrase it euphemistically.

He told them it was false. That's what they were doing.

And there was actually a third aspect of this that -- we went back. I'm going to go back here. So we are also going to introduce evidence that they interacted with the regulators in a way that we think was not ethical.

Instead of actually legitimately participating in the science, you're going to see that the CTFA and Johnson & Johnson and maybe some other participants in the industry acted to confound the regulators.

Every time the regulators would try to make talc recognized as a carcinogen, Johnson & Johnson and sometimes some of its friends would get together and go on this blitz and try to stop that from happening. And, quite frankly, you will see evidence that was successful.

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So in this courtroom, what I'm going to tell you is that the evidence shows this is all like a house of cards for Johnson & Johnson. They told people that their product was pure and safe. It was neither pure nor safe. They told women that this was best for your baby and best for you. That wasn't true either. They said you could use it face to feet. Not true. They said that it didn't have asbestos in it, but you will see evidence in this courtroom that it did. They said it doesn't cause cancer, but you are going to hear testimony and see evidence in this courtroom that it did. And that it caused cancer in my client, Marilyn Seskin.

And then they deny, they deny, and they deny it. And all of this is going to fall down with a single piece of evidence. So for years you will hear evidence in this courtroom that Johnson & Johnson interacted with the FDA, with the Food and Drug Administration. And the FDA would occasionally test talcum powder products, not just Johnson's baby powder but other talcum powder products as well. And for a long time the FDA had never been able to find the asbestos. And there will be debate about why that was. Our experts found it and you will hear some testimony about that.

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But something incredible happened in 2019. Well, back up a little bit. 2018. In 2018, the FDA reached out to Johnson & Johnson, and said, We are working on this issue. Can you recommend a series of experts for us? And Johnson & Johnson sent them a letter back and said, sure. They recommended three experts.

The first expert on the list was a gentleman named Dr. Andreas Saldivar. He worked with AMA Labs. Johnson & Johnson used him in litigation cases just like this and recommended that the FDA use them. They didn't know what the FDA was going to do with them, but the FDA hired them.

So in 2019 Dr. Saldivar gets a bottle of baby powder off the shelf and he tests it. And do you know what he finds? He finds chrysotile asbestos in that bottle. Okay. You are going to hear evidence in this courtroom that Johnson & Johnson, from their own witnesses, asked Dr. Saldivar to withdraw those results and asked the FDA not to finalize those results. They didn't withdraw them and they finalized them.

It gets better. So the evidence is going to be that Johnson & Johnson knew it had a problem. they got an executive. They put him on a private

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jet, and they sent him down to Royston, Georgia. What is in Royston, Georgia? Royston, Georgia, you will hear, is where Johnson & Johnson bottled baby powder.

So at the bottler's factory -- you've got a bottle FDA tested from the shelves, right? Royston, Georgia, you've got what is called a "control sample" where they bottle a lot of baby This is not just Johnson & Johnson, it could be any product. They keep a control sample for, you know, litigation like this or recalls or whatever. They had issues that they need to keep it back there. So this is something kept in a totally separate place thousands of miles away.

Johnson & Johnson says, Well, we figure if we can prove that control sample is clean, we've got no problems right? It could have been a contamination somewhere out in the world. They take that sample, they put it on the private jet, they send it to RJ Lee labs. You may even hear from RJ Lee labs in this It's one of their favorite labs. What do they Chrysotile asbestos. The first test they run, find? they find chrysotile asbestos in that control sample.

Now, I don't want you to think that is the last Johnson & Johnson has a response to that. word.

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They ask asked RJ Lee labs to retest that sample, and then blamed it on contamination from an air conditioner in the room. But what you are not going to hear is any explanation from where that asbestos came from, how it got on that air conditioner, or why that lab violated its own protocols. And common sense is going to tell you that you know what happened. The bottle had asbestos in it, and the control sample had asbestos in it.

So I showed you the road into the courthouse. It's my job and my team's job to show you the road out of the courthouse, which is, you know, what your job is and how you're going to make your decision.

So in order get out of the courthouse, we have got to resolve this dispute. I am going to bring you evidence about Marilyn Seskin's talcum powder use over her whole life. There are three sources that you will hear this from that are, I would call, primary sources.

Our experts will talk about it, but they are going to be relying on a sworn statement that Marilyn filled out I think about two weeks before she died.

Her husband, Bob -- she wasn't well enough to even write, really, so he would ask her the answers (sic), he would write the answers down for her and she

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signed. She signed the sheet. So you are going to see that. And that's going to talk about her usage some.

You are going to hear from her husband, Bob.

Bob is going to tell you that he did the laundry at their house, he saw the baby powder in her underwear when he did the laundry in their house. He obviously saw Johnson's baby powder around house. He knew that she used it as a deodorant. I believe he is even going to testify she wouldn't use a normal chemical deodorant like Right Guard, like I use, because she thought that it might have some harmful effects. So she used baby powder.

He's also going to talk about her using it on her diaphragm. His testimony will be that she used it two to three times a day. If she showered twice a day, she would use it twice a day.

She used it liberally. He is also going to tell you she trusted the Johnson & Johnson name. And you are going to hear testimony that in close to the time of her death she did not understand the connection yet between baby powder and her ovarian cancer, but she had ovarian cancer. She was going to go out of town, and the evidence will be, she said, Bob, I need you to get me some baby powder. Well,

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Bob went to the store -- and if you're a husband, you have probably done this; if you're a wife, you have probably had your husband do this -- he got the wrong thing, some off-brand powder. He brought it back, and he said, Here's the powder. And she said, No, I don't want that. You got to get me Johnson's baby powder. So she trusted that product.

You are also going to hear evidence from her college roommate, because Bob and Marilyn were married late in life. They met in the early '90s. So we got the testimony of her college roommate who said, When we were in college, she always had a bottle of baby powder in her dorm room. We would go on camping trips on the weekends. The girls change behind one bush, the boys change behind another after we were swimming and she used baby powder.

If I recall correctly, the roommate is going to say, I thought that was an odd practice for a college student, but I saw her do it and she really believed in the stuff. And sort of said, Hey, do you want some? And Diana Ronell said, No, I'm okay. But we're going to show you that she used this product her whole life.

So how are we going to prove that the product did her any harm? Well, you're going to hear from a

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series of expert doctors and scientists. The first expert you are going to hear from -- he is going to testify by deposition; that means we have a videotape of him -- is a treater and surgeon who took out Marilyn's cancer.

His name is Dr. Thomas Morrissey. And Dr. Morrissey is going to tell us a couple of very important things. The first thing he is going to tell us is that her cancer was high-grade serous cell carcinoma. High-grade serous cell cancer. Why does that matter?

The doctors are going the tell you that that cell type is the one that is most frequently associated with talcum powder use. Cancer -- and I'm not the expert -- but cancer basically has sort of two aspects to it. There is the cell type and there is where it originates or where it shows up. Both of those things will be a subject of this case. But she had the type, high-grade serous cell, that is most associated with talcum powder use in the literature.

This is Dr. Morrissey's record. He is also going to tell you that there was cancer on the surface of both her ovaries, and that he diagnosed her with primary peritoneal cancer.

This is on her certificate of death.

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certificate of death calls it metastatic fallopian tube cancer.

Why am I telling you all this? I am telling you all this because I anticipate that our experts will testify that primary peritoneal cancer and ovarian cancer of this nature, high-grade serous cell, all start in the fallopian tubes. And when those cancer cells develop in the fallopian tubes, they then migrate into the ovaries or the peritoneum or both. In Marilyn's case, it was both.

But I expect the defendants' experts are going to make a big deal and say that primary peritoneal is not the right type of cancer. It is ovarian cancer. Each of our experts will explain that they use these terms interchangeably, they are treated the same, and it is the appropriate cell type that was caused by Johnson talc-based baby powder.

And this is just a diagram to show you. This is the peritoneum, the lining of that body cavity, and this, these little yellow spots would be if you had primary peritoneal, you would have some on your ovaries, and you would have some in your peritoneum.

So the last part of our case -- I have got to go back to my expert. Sorry.

So our next expert is Dr. Arthur Sitelman.

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Dr. Sitelman is a pathologist. He is going to confirm what I told you about the cell type. But he is also going to say something very important.

Dr. Sitelman used a special microscope called a polarized light microscope, we'll call it PLM. And he looked at tissue slides of Marilyn's ovaries and her peritoneum under that microscope.

The reason he did that is because if you look at tissue under PLM, there are a limited number of particles that will be called birefringent.

Basically, he will tell you, in layman's terms, that means they sparkle. So there is only a limited number of things that will sparkle. Sand is one of them, for example. He will tell you some of the others.

But talcum powder particles are also one of those things that sparkle under that microscope. And he is going to tell you after looking at multiple tissue slides from Dr. Seskin, he looked in the literature, he understood her usage of the powder, and he saw those particles, and they were the right shape, the right morphology to be talcum-based baby powder, and he believes those are talcum powder particles embedded in her tissue from years of use of Johnson's baby powder.

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The next expert gentleman named Dr. Mark
Rigler. Dr. Rigler is a PhD. He is not an MD.
Dr. Rigler's training is in microbiology, but you
might hear him refer to himself as a material
scientist. He goes into different areas and looks
for minerals in people's tissue or in different
products.

So if you wanted to identify whether a product had silica in it, Dr. Rigler knows how to do that. If you wanted to figure out whether insulation had asbestos in it, Dr. Rigler and his laboratory know how to do that.

So what did they do in this case? Dr. Rigler and one of his colleagues gathered up, I believe it was 70-something bottles of baby powder, and they also got some rail car samples from the mine that produced baby powder during certain time periods. He will tell you that they gathered these bottles from, I believe, the '50s, the '60s, the '70s. They went all the way up to even the '90s or the 2000s.

And he tested those bottles of baby powder and those rail car samples, and he found asbestos and he found fibrous talc in between 70 and 72 percent of the bottles he tested in the rail car samples for Johnson's baby powder.

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So the next expert we have is a woman named Dr. Ness. Dr. Ness is incredibly important because in this courtroom, you are going to hear Defendants talk a lot about the studies that I mentioned. There is going to be a lot of discussion about the studies.

Why? Because I anticipate the defendants will want to criticize those studies. Dr. Ness is so critical because of all the witnesses that will show up in this courtroom, she is the only one who has ever done one of those epidemiological studies. She is one of the researchers that has done that work, that has done the math, that has gathered the information, and published and said, There is a statistically significant association between this product and ovarian cancer.

And she will explain what we in the legal profession call general causation. She is going to explain to you just how the product causes cancer. She is not going to talk about Marilyn. She didn't look at that. She is going to tell you about the research. She is going to tell you about how this product leads to primary peritoneal and ovarian cancer in women like Marilyn Seskin. And she is only one in this courtroom who ever did one of those studies.

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Now, the final doctor is Dr. Chan. Dr. Chan is He did not a specialist in gynecological oncology. treat Marilyn Seskin, but he is a specialist in that. And he is going to tell you that he looked at the testimony in this case, he looked at the medical records in this case, he considered all of the risk factors that Marilyn Seskin did or did not have in this case, and that he believes that Johnson's talc-based baby powder, her use of that product, was a substantial contributing cause to Marilyn's cancer and death.

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And he looked at all of the things the defendants are going to talk about. They are, of course, going to point to all manner of other things. Dr. Chan considered those things, and at the top of his list was Johnson's talc-based baby powder.

So the final element of our case is going to be my client's damages. And damages, in this case, I want you to understand, are about Bob's pain and suffering. That is what Florida law says. It is not about her pain and suffering. It is about what my client went through when he was with her through three years of chemotherapy and surgeries and what he's gone through after without her.

This is obviously not a picture of Bob. This

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is somebody -- Marilyn learned to play quitar. took guitar lessons, and this is somebody who, near the time of her death, Bob got to come and play her Beatles songs because she liked that.

You are also going to hear that while Bob was by her side, one of the doctors actually said to him -- let me get this right. It is very difficult.

So at the end of her life, Marilyn was told she needed to go to hospice. And she didn't want to go to hospice because we all know what hospice means, and I told you Marilyn was an anesthesiologist. she knew all too well what that meant.

So Bob ran around the hospital. He knew some of the executives. He knew some of the doctors. You've got to keep her here. You can't put her in hospice. You can't put her in hospice. And one of the doctors, he'll testify, basically said, Look, if you don't go home, I am going to have two patients, not one, because he was driving himself into such a state with what was going on with her that he was going to end up in the hospital.

So Bob is going to tell you about that. is the best I can do. I can't do a better job than he will do, and you are going to hear that directly from his mouth.

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I want to leave you with a final thought. And the final thought is this: There are going to be a lot of questions for you at the end of this case. These questions aren't going to be on your verdict form. But I think that as you listen to all of the evidence that you hear from the defendants and from the plaintiffs, you can decide this case by asking three questions every time a piece of evidence comes up.

The first question is: Who is telling the truth? Why should I believe this person or not believe them?

The second question is -- and I am going to forget my second question.

My second question is: What does my common sense tell me, right? And it is just like that 2019 testing. It is like, Hey, they found it in the bottle, they found it in the lab, and then Johnson & Johnson came up with some explanation. Common sense tells you where that goes, right? It doesn't make sense.

And then the final is: What is the right thing to do? If you ask those three questions with every piece of evidence and every witness and every argument that the lawyers make, then I think at the

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Page 536 1 end of this case, you are going to agree that I 2 proved my case for my client, and that he is entitled to the things that we will ask for at the end of this 3 case. 5 I know you guys have been very patient. you for your time. And even though I don't agree 6 7 with the defense lawyers, I would ask you to give them the same attention you have given me. So thank 8 9 you. 10 THE COURT: Thank you, sir. 11 Do you all want to stand up to stretch your 12 legs for just a moment? 13 And the defense can get set up, ready to do 14 your opening argument. 15 MS. BROWN: Thank you. Thank you very much, 16 Your Honor. 17 (Jurors exited the courtroom.) 18 (Jurors entered the courtroom.) 19 THE COURT: All right. For the record, all of 20 our jurors are present. All the parties are present. 21 You may begin your opening statement. 22 MS. BROWN: Thank you very much, Your Honor. 23 Good afternoon, everyone. Thank you for coming 24 back today. My name is Alli Brown, and I am here 25 with my colleague and my good friend, Hassia

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Diolombi, on behalf of the folks at Johnson & Johnson and LTL.

So this morning, you heard the plaintiff's lawyer just say some really bad things about Johnson & Johnson, and he made some very serious allegations about the people who worked there. He accused us of selling a product for babies that causes cancer.

And, unfortunately, sometimes that can be an easy thing to do. It can be easy to point the finger at a big corporation like ours because lots of people don't like corporations. And you guys heard that when you were here yesterday, right? You heard some of your fellow jurors who were really honest with us and who raised their hands and said, I don't like corporations. I think corporations get away with too much.

But you guys are back with us today because you said that you could be fair. You said that you could put aside anything that you have heard in social media, on the news, any personal experiences you have had with corporations in your life, and judge this case on the evidence and on the facts.

And the evidence and the facts and the science and the truth in this case is going to be that Johnson's baby powder did not cause Marilyn Seskin's

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very, very rare peritoneal cancer.

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And one thing I want to make very clear to you all from the beginning is that there is nothing that Hassia and I do in defending this case and in proving to you that Johnson's baby powder was not responsible for Marilyn Seskin's cancer that is in any way meant to disrespect Dr. Seskin, Mr. Sugarman, or take away from the pain that that family obviously went through, because cancer is a horrible disease.

And so in proving to you that Johnson's baby powder had nothing to do with her cancer, we in no way meant to take away from the pain that Mr. Sugarman and the whole family has obviously been feeling.

But you are here in the courtroom now, and we have been sued for something that we did not do. because Mr. Sugarman has brought this lawsuit, plaintiff, and plaintiff alone, has the burden of proving to you that the claims that they made in this lawsuit are true and are supported by the science and the evidence.

And we spoke a bit about the burden of proof yesterday, and we talked about how their burden is to get over 50 percent, to prove to you all that it is more likely than not that baby powder was the cause

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of this rare cancer.

But to be clear, their scale doesn't already start at 50 percent. When they come into this case, there is nothing on their scale. They have to give you enough evidence to get that scale all the way up past 51 percent.

MR. OLIVER: Objection. Misstates the law.

THE COURT: Ladies and gentlemen, the Court will tell you what the law is.

And this should just be your opening statement.
What is the evidence going to show?

MS. BROWN: Yes, Your Honor.

And what the evidence is going to show is that plaintiffs cannot establish, because it is not the truth, that Johnson's baby powder was responsible for this cancer.

But what I am afraid is going to happen and what we already saw happen in front of you all this morning is that there is going to be an effort to get you so mad at a big corporation that you turn away from the facts and you turn away from the evidence and you turn away from the science. And I think the way that is going to happen is by cherry-picking little bits and pieces of documents to try and suggest to you they say something that they don't.

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And I want to just show you a couple that happened right here this morning to give you an example of what I think is going to go on in this trial.

If I could have the ELMO, Mr. Morales, for just a minute.

So counsel shared these slides with me this morning, and this is one of the slides that went up for you all to see. As counsel was arguing to you that we knew in 1969, there is asbestos in baby powder. And he put up this document, and the title of it is, "Johnson & Johnson Admits Asbestos in Talc." And what he didn't tell you and what he didn't show you is this document is titled "Project 101. Alternate Domestic Talc Sources."

What he didn't tell you, but what he knows because he has the documents, is that Project 101 was an effort to find the very best mines that we could to use talc in our baby powder. And what he didn't tell you, but he knows it because he has the document, is when we found out that those mines could have something called tremolite, we terminated the project.

He showed you a document about the Grantham mine that we abandoned that we decided didn't have

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enough high quality talc to be able to use in our baby powder. But he put it up there as if it was evidence that we knew there was asbestos in Johnson's baby powder. And that is just not the truth.

Another thing that you saw this morning was a suggestion that our own consultant was telling us that the trade association was saying things that weren't right. And this was another example where this document wasn't put in front of you in its entirety, but you sort of got this clipped-out piece. And it doesn't represent what this entire document said. And it was put up there to suggest something to you that's not true.

It was put up there to suggest to you that Dr. Wehner had concerns about talc, about the safety of talc. But when you look at the whole document -- and I am going to make sure that it comes into evidence so you could see the whole document -- you will get to see what this document really is all about.

You see, Dr. Wehner was a consultant for us, and you're going to hear we had a lot of consultants along the years who helped us look at the science and make sure that we were keeping up with the literature. Dr. Wehner was one of those doctors. He

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even published a paper reviewing all of the scientific literature on talc.

And what Dr. Wehner was upset about in this

1977 document that went up on the screen is that the

trade association wasn't doing a good job explaining

the scientific literature. He felt so strongly about

this scientific literature that he was critical of

the way the CTFA, or the trade association, was

describing it.

And the part of the document that you didn't see in that little piece that was clipped out during the presentation is this. What he talks about is the workshop. This workshop was a 1994 two-day symposium sponsored by the FDA as well as industry. What he's saying is the workshop did conclude that the results of these studies were ambiguous, inconsistent, contradictory, and therefore inconclusive.

Therefore, hygienic use of cosmetic talc does not present a risk to the consumer. So why not use these powerful and irrefutable arguments instead of questionable mush that leaves one vulnerable to counterattack?

He believed in the science, and this letter is all about how he thought we could better explain the science, not how he thought people were making false

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statements.

And there are a number of other examples that went -- what went on here this morning. And so one thing I will ask of you all is you listen to the evidence come in is to wait for us, because the way this works is we have to go second because we got sued. We're the defendants, but wait for us to make sure that we can show you things, like what the rest of these documents show, because I'm afraid there is going to be an effort to continue on what happened here this morning.

If I could go back to the PowerPoint, please.

What the evidence unquestionably is going to show, folks, is that Johnson's baby powder did not cause Marilyn Seskin's rare cancer. Johnson's baby powder has been used safely for over 125 years.

You're going to hear that Johnson's baby powder first came to market in 1894. Johnson & Johnson itself has been in existence since the late 1800s. And what the evidence is going to show is that you don't stay in business as long as Johnson & Johnson has by doing the types of things that were alleged here this morning, by selling a consumer product that causes cancer.

We employ over 40,000 people in the United

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States. You heard many jurors yesterday or some of the folks that we employ right here in Miami. And over 150,000 employees worldwide.

And one of the things that's just not going to make a lot of sense to you all as you sift through the evidence in this case is this, Johnson's baby powder is a very common product. Almost everyone has used or knows somebody who has used Johnson's baby powder. Hundreds of millions, if not billions, of people in this country and around the world have used the product.

But the disease that plaintiffs -- and you're going to hear the disease that plaintiffs claim that it causes is extraordinarily rare. So there are over 160 million women in the United States. Each year only about, thankfully, 18,000 women are diagnosed with ovarian cancer. So that's like 0.011 percent of women, an extraordinarily rare disease.

But Ms. Seskin didn't have ovarian cancer. And you're going to see that was important to Ms. Seskin. This is a note that she wrote to her doctors. You are going to see she was very involved in her medical care. And one of her medical records accidentally said that she had ovarian cancer. And she sent this note back and said, Hold on, the diagnosis is not

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correct. I don't have ovarian cancer. The pathology was specific for primary peritoneal cancer. It is just treated the same.

And that's true and you will hear that. These are cancers that are treated in the very same way. But the reason it's important is that primary peritoneal cancer is even more rare than ovarian cancer. So while only about 18,000 women are diagnosed with ovarian cancer each year, only a little more than 1,000 women, thankfully, are diagnosed with this disease every year. That is 0.0007 percent. It is an extraordinarily rare cancer.

And so one of the things that is just not going to make sense is that if this very, very common product that we were all exposed to caused primary peritoneal cancer, where is the epidemic of primary peritoneal cancer? Why are there only 1,000 people being diagnosed with the disease each year? It doesn't make common sense. The theory of the case doesn't make common sense.

What you are going to hear is that public health authorities like the National Cancer Institute have identified risk factors for ovarian cancer and primary peritoneal cancer. And what you're going to

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hear is that Ms. Seskin unfortunately had many of those risk factors. What the evidence is going to show in this case and what is the unfortunate truth is that, like a lot of things in women's health, this is a women's health issue. This is a women's health disease that we do not know the cause of. We do not know what causes ovarian cancer. But we do know some things that put women at risk. And unfortunately Ms. Seskin had many of those things.

Being over 50 puts you at risk. The average age of diagnosis for ovarian cancer is about 63. Primary peritoneal cancer is a little bit older.

Ms. Seskin was 66 years old when she was diagnosed, right about the average age for diagnosis. Not having kids -- and we'll talk about the science during the case why it is -- but not having kids actually puts a woman at risk for ovarian cancer.

And Ms. Seskin by choice did not have children, and unfortunately that put her at risk.

Never using birth control puts you at risk for ovarian cancer and primary peritoneal cancer. And that was the oral contraceptives, like the birth control pill. And that was the case, unfortunately, for Ms. Seskin. And so she had these first three risk factors. But she had others as well.

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Hormone replacement therapy can put -- and this is the list from the National Cancer Institute, and we'll talk about it. They don't recognize talc.

They don't believe there is evidence that talc puts you at risk for ovarian or primary peritoneal cancer.

But when it comes to hormone replacement therapy, what you're going to hear is that, as a doctor, actually, Dr. Seskin prescribed for herself her own hormone replacement therapy. And you will get to see the medical records because her doctors actually were a little concerned about it. She was prescribing HRT that she would fill at a compounding pharmacy at levels that caused her hormones to be high.

And you will get to take a look at those medical records, and you will see her doctors' concern about some of that. But this use went on for 18 years. And the literature and the public health authorities also recognize that, unfortunately, as a risk factor.

Dr. Seskin also had undiagnosed endometriosis.

You will hear that is another risk factor for ovarian cancer and for primary peritoneal cancer.

Then we are going to talk a bit in this case about genetic factors. So these factors were

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considered by Dr. Seskin's treating physicians. And one of the genetic mutations you all might be familiar with, BRCA1 one BRCA2. Dr. Seskin did not have those.

But there were other genetic considerations that her treating physicians looked into. One, because she was of Ashkenazi Jewish descent, and you are going to hear there is literature that being of Ashkenazi Jewish descent can increase a woman's risk of these cancers by up to 10 percent. And so her treating physicians, this was part of her genetic consultation.

And then you are going to hear she was tested for genetic mutations and had a genetic mutation called FANCC, F-A-N-C-C, or FANCC or FANCC sometimes is sort of the shorthand to it. And you are going to get to see her own notes of what she thought about that genetic mutation. This is Dr. Seskin's notes. And it says FANCC gene could possibly have caused this, may be the underlying explanation.

And you are going to hear that when it comes to FANCC, science is developing, and I'm not suggesting to you that that's the cause or that is what you are going to hear, but you're going to see what Dr. Seskin thought about that and what her genetic

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counselors thought about that.

This is a case where no treating physician has concluded the facts that the plaintiffs are alleging in this case. Dr. Seskin, fortunately, and we will talk about it, got some of the very best care in the country and even beyond. They were able to consult with physicians even outside of our country. And not one of them concluded that talcum powder caused her primary peritoneal cancer.

You are going to hear that she was treated at the Cleveland Clinic, and the Cleveland Clinic has a list of what causes ovarian cancer. And what they start with is what we know is the unfortunate truth. The exact cause of ovarian cancer is not yet known.

But they have a list very similar to the one we just looked at from the National Cancer Institute.

Not being pregnant, endometriosis, being over the age of 60, these are things that put you at risk for ovarian cancer and primary peritoneal cancer. The Cleveland Clinic does not recognize talc as a risk factor for ovarian.

She was also treated at MD Anderson or sought consultation at MD Anderson. They, too, recognize the similar risk factors for ovarian cancer: Age, family history, some genetic mutations, not having

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children. They do not recognize talc as a risk factor.

She was treated at Dana-Farber in Boston.

Again, family history, hormone replacement,

nulliparity, which means not having children.

She was also treated at the Cancer Institute of America. There was some consultation there. And you are going to get to see they, too, recognize the very same risk factors and do not recognize, because the science doesn't support it, that talc is a risk factor for ovarian cancer or primary peritoneal cancer.

And also back here at the University of Miami
Health System, also treated there. And you are going
to hear, really, about some of the great work that
Mr. Sugarman did in facilitating Ms. Seskin being
able to go to all of these different institutions to
be able to get the very best care that she could, but
that none of these institutions recognize what they
are claiming in this lawsuit was the cause of ovarian
or primary peritoneal cancer.

You will get to hear from some of her treating physicians. Dr. Thomas Morrissey was her surgeon, and he did a videotaped deposition that you will get to hear about. And he is able to tell you he did not

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conclude that talcum powder was the cause, he did not recommend that anyone bring a lawsuit against Johnson & Johnson for talcum powder, and that he endorses and agrees with the National Cancer Institute when they say that there is inadequate evidence that talc can cause ovarian cancer or primary peritoneal cancer.

You are going to hear Dr. Brian Slomovitz who was one of Dr. Seskin's treating physicians, and you are going to be able to see an article that he's written in the scientific literature criticizing studies that try to link asbestos to ovarian cancer. You will get to see his thoughts on some of the allegations that are being made in this case, published in the scientific literature.

And what you are going to see are the medical records where Dr. Seskin's own doctors recommended that she use cosmetic talc, even after she had been diagnosed with cancer, even after she had been diagnosed with cancer and was unfortunately undergoing chemotherapy, she was experiencing chafing on her skin. And what did the doctors recommend? That she use cosmetic talc, a way to prevent this. You'll see, these are her notes of the medical records, use Gold Bond medicated talc.

And one of the other pieces of information that

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you are going to have to sort through and figure out if it makes sense is that both Marilyn Seskin and Mr. Sugarman continued to use cosmetic talc, even after they decided to bring the lawsuit against us alleging that we had caused this cancer.

Document 2648-32

PageID: 97200

You are going to hear that even after the decision was made to sue us, Marilyn Seskin continued to use Johnson's baby powder in the very same way she had been doing and continued to use it all the way up through her unfortunate passing.

And you are going to hear, at least as of the time that we were able to ask Mr. Sugarman questions in something called a deposition, years after Marilyn Seskin had passed away, he was using cosmetic talc himself.

So you are going to have to sort through whether that makes sense, whether he really believed that a product has asbestos and causes cancer, you would still use it yourself. You would still keep it in your house. You would still let your loved ones use it. You are going to have to sort through that evidence and figure out whether that makes any sense, whether that supports these lawsuit claims.

You are going to hear that this guestion about whether cosmetic talc can cause ovarian cancer or

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primary peritoneal cancer, it is not a new question. This is a question that was raised by scientists decades ago, and it has been studied in epidemiology-like studies of people, in cell studies and animal studies, literally for decades.

You are going to see studies from the '80s, the '90s, the 2000s. This is something that has been well studied and proven conclusively not to be supported by the science.

You are going to hear about two different types of studies in people, forward-looking studies and backward-looking studies. So these epidemiology studies happen in two ways, essentially. Women who are already diagnosed with cancer can be asked, Well, you now have ovarian cancer. Did you drink coffee? Did you dye your hair? Did you use talc for feminine hygiene? Those are what are called backward-looking studies.

And there are some limitations on those studies because once you have been diagnosed with cancer, as you can absolutely understand, sometimes you are really trying to find a reason for it. And so when you are asked to look back and recall what you ate, what you did, did you dye your hair, your recollection could be biased. And it is a phenomenon

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called recall bias that is mentioned in all of those studies, and we will talk about it.

The better studies are the studies that just follow women, that just say, Let's fill out a questionnaire as you go through life, and every year tell me, you know, are you drinking coffee? Are you drinking alcohol? Eating hamburgers? And you don't, sort of, have that recall bias because you are not sick. You are just telling what you are doing.

And those studies have been done by our government, not by J&J, by government organizations and have consistently shown no association between talc and ovarian or primary peritoneal cancer.

One of the first ones that may be familiar to you all is the Nurses' Health Study. Big women's health study, almost 80,000 participants.

Questionnaire ran '82. There was a follow-up study that went through 2010. No association with talc use in ovarian cancer. Follow-up study was done.

Another big women's health initiative that you may all be familiar with, the Women's Health Initiative study. Perineal or feminine use of talc not associated with ovarian cancer. This had 61,000 women.

And then there was a 2016 forward-looking

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study, the Sister Study, that found -- and this was interesting -- it found, actually, douching was associated with ovarian cancer, but talc was not. And one of the reasons the epidemiologists are going to tell you that is an interesting finding is because it suggests that there might have been something that was confounding the earlier studies on talc.

So if you were looking -- there might be something about women who use talc that could actually be driving the increased risk, and this study identified douching that nobody had ever thought of up until that point. So this was an important study that you will hear about.

But this wasn't it. Just recently in 2020, authors came along and published in JAMA, one of the most prestigious medical journals, a pooled analysis of all of this forward-looking data and some unpublished data to date. They put it all together and said, Let's increase the power of these studies, and let's see if we can find an association.

And what they found with over 252,000 participants, over 3 million person-years, sponsored by our government, no association between the feminine use of talcum powder and ovarian cancer or primary peritoneal cancer.

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What their case is going to be based on are a handful of backward-looking studies that took place many years ago and that reported to show a small increased risk. And each one of those studies shows recall bias.

Document 2648-32

PageID: 97204

And the experts are going to talk about how, statistically, they show it in the study, but you will be able to see the studies themselves that identify this entire small risk that we are reporting here could be due to recall bias, could be due to the fact that we asked women after they already had cancer whether they used talc, and their recollection, understandably, might not be that good. And the epidemiologists will talk to you about those.

And that is why IARC, this international organization whose purpose is to classify things that do cause cancer or probably cause cancer or only possibly can cause cancer, put perineal use of talc in this low, limited evidence category with aloe vera and pickled vegetables. And the reason they said it is because this bias or confounding couldn't be ruled out of some of those early studies.

I am going to skip through this so we can keep going. We will talk about this with some of the experts.

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This is also critical when we talk about the scientific studies because the bulk of the exposure that is alleged in this case is from a talc-dusted diaphragm. And, interestingly, these studies examined that type of use specifically. They said, Let's look at women who specifically use talc on their diaphragms. Is there any increased risk?

Document 2648-32

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And they consistently said no, and this last study actually found it to be protective. actually found women using talc on their diaphragms had a statistically significant decreased risk of primary peritoneal cancer and ovarian cancer.

So aside from the forward-looking studies that address these cancers overall, the studies that look at the particular way that Marilyn Seskin used this product find no risk at all. There is not a single epidemiology study that concludes cosmetic talc causes ovarian cancer or primary peritoneal cancer.

You are also going to hear about the cell studies that have been done. So in addition to studying humans, scientists have said, Well, you know if we take a petri dish of cells and we sprinkle talcum powder on it, do the cells start to change in a way that could be consistent with causing cancer, precancerous changes?

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And the studies over the years uniformly show no malignant transformation, cancerous transformation. Are they looking like they are starting to cause cancer? No. Nothing is happening. The talc is going on the cells and literally nothing is happening. Nothing, nothing, nothing, nothing.

Last year, someone reported to say, Oh, we found malignant transformation. We think we have discovered talc causes cancer. And this is truly remarkable because this study was paid for by one of the law firms of one of the plaintiff's lawyers in this case. So once the litigation started, the lawyers paid this guy to do this study, and you will see the disclosure.

And the real scientists who had a look at this article to decide whether it should be published were outraged, absolutely outraged. And you are going to get to see their comments where they say, The authors -- so first of all, this is the article, right? "Paid for by lawyers representing plaintiffs in talcum powder litigation." It is actually some of the lawyers you will see in this case.

The author -- this is what the real scientists in the real world say when they look at this stuff.

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"The authors' conclusions suggesting that exposure to talcum powder is associated with ovarian cancer are outrageous and not supported by the data. The science, the methodology, and the data cannot be trusted."

The cell studies uniformly show no malignant transformation, except for the one that can't be trusted.

And then you will also hear about animal studies. Another way to know this product doesn't cause cancer is you will look at what happens in animals. You will hear about animal studies that were done looking specifically at -- rats don't have ovaries per se, they have bursas, and these studies look at whether or not there were changes in the bursas of the rats and there were not.

And then on this issue with asbestos, you are going to hear a ton about asbestos, there were animal studies done with our talc, the talc that we put in the baby powder, and they said, Okay, let's take the -- I think it was rats or maybe hamsters in this one, they said, Let's inject the animals with asbestos and let's see if they get mesothelioma, an asbestos-related disease. And let's also inject them with Johnson talc and let's see what happens.

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And as you would expect, when we injected them with asbestos, they got the asbestos cancers. When we injected them with our talc, nothing happened. The same thing -- they got the same result as with the saline, which was the control group.

So you are going to see evidence from people studies, cell studies, animal studies that will prove to you that this product does not cause cancer.

Nobody who is in charge, not of litigation, but in charge of our public health in this country concludes that talc causes ovarian cancer or primary peritoneal cancer.

And I can assure you folks it is not because they have not been looking at this issue. You are going to hear about a robust history of oversight from the FDA. Starting back in the 1970s when this idea that talcum powder might be contaminated with asbestos first came up. It came up and you will hear about how scientists thought they were reporting asbestos in baby powder, and everyone went -- the alarm bells sounded, as you can imagine. And the FDA sprang into action, and they did testing in the '70s, they did testing in 2010. We will talk about how sensitive their testing was in 2019, they picked up three fibers of contamination. And how they

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continued to test in 2021, not our talc, but 2022, no asbestos.

You are going to hear about a long history. And you are going to hear about something called a citizen's petition, which is going to be important to some of the allegations in this lawsuit. You are going to hear that citizens can write the FDA and say, FDA, we think you should put a label on a product, remove a product from the shelf, this is what we think you should do. In 1983, a cancer group wrote the FDA and said we think there is asbestos in baby powder, cosmetic talc. We think you should put a warning on it. And you're going to hear about all the work the FDA did to evaluate whether or not that claim could be true. And you will hear about their conclusion that there is no basis to conclude that there is asbestos in cosmetic talc or there is a health hazard, and that no warning would be appropriate.

You are going to hear in one of those letters that you saw parts of this morning referenced this 1994 meeting. Two-day workshop, over a hundred scientists, fifty of them from industry, forty of them from universities and government, looking at this issue. Right? The first day was whether there

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was an inhalation risk with talc, the second day was whether there was an ovarian cancer risk. And then they published their findings and you will get to see them during the trial.

This is what they conclude: In joint evaluation, talc is proven to be one of the safest of all consumer products. To reasonable people. Even armed with reasonable concern for prudence, these clues suggest that the probability of human risk is likely nonexistent under customary conditions of use.

You're going to hear, specifically to ovarian cancer, about another petition that was filed in 2014 asking for an ovarian cancer warning on talcum powder. You're going to hear about the robust evaluation that the FDA did, and how the FDA denied that petition because there was not adequate science to support it.

Those are the claims that are being made in this lawsuit, that there should have been an ovarian cancer warning on the product, and the FDA looked at that in 2014 and said no, the science doesn't support it.

Real quick, I want to run through with you what our public health authorities say about this issue.

National Cancer Institute as a public health

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service analyzes and groups risk factors for different cancers. For ovarian cancer, they have factors that are adequately associated with ovarian cancer. They have factors that we aren't sure about, uncertain factors. And then they have factors that there is inadequate evidence that it could be associated with ovarian cancer. And that is where perineal talc exposure fits.

The data is inadequate to support an association between perineal talc exposure and increased risk of ovarian cancer, and in this, when you get to see the document, you will see when they are talking about ovarian cancer here, they are also including primary peritoneal cancer.

American Cancer Society, weight of the evidence does not support an association between ovarian cancer and genital exposure to talc-based products.

This is the Society of Gynecologic Oncologists.

They, too -- so that is all of the cancer doctors who take care of people who have ovarian cancer or other gynecologic cancers like primary peritoneal, fallopian tube, uterine. They have a society.

Doctors do not know what causes most ovarian cancers. They, too, do not recognize talc as a risk factor.

The American College of Obstetrics and Gynecologists,

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or regular OB/GYN, have their own society, do not recognize talc as a cause, and in fact have a statement that there is no medical consensus that talc causes ovarian cancer.

Our Centers For Disease Control actually does not recommend talc as a risk factor, but believe it or not, they recommend genital use of talc as a treatment for genital warts. This is on their website now. This is from 2021, still on their website today. Recommending this use, our Centers For Disease Control.

Just like with the epidemiology, no United
States public health authority concludes that
cosmetic talc causes ovarian cancer or primary
peritoneal cancer. The evidence is going to be
overwhelming that the science does not support the
claims that are being made in this lawsuit.

I want to leave you with one final section. I know we have been doing a lot of talking at you today and we did a ton of questioning at you yesterday, so I really appreciate you guys being so attentive. But I do want to talk a little bit -- because there was a ton of allegations about asbestos and fibrous talc -- about some of the things that we did to ensure that Johnson's baby powder was safe and did not contain

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asbestos.

First of all, you are going to hear about picking a mine where we got our cosmetic talc from -- was an enormous process that took many years. It wasn't a situation where we said, all right, this mine looks good, let's put this in baby powder.

You're going to hear about all of the testing that went on before we even approved a mine to be suitable to get talc from to put in our baby powder. And that is what that document I started with showing you was all about. We had a whole program looking for alternative mine sources. And when we found that the talc wasn't suitable to our quality standards, we rejected it.

So you are going to hear about the qualification of the mine and the testing that went on at every single step of the way. For some period of time, we owned the mine in Vermont here, and for some period of time we bought talc from a supplier. And what you are going to hear is when we bought the talc, we demanded that it meet our specification, that it be tested to be asbestos-free, that it had all sorts of other requirements to meet our quality standards.

But that is not where we stopped. Because we

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sort of checked the work of these folks who were telling us they were selling us asbestos-free talc. And the way we kid it was by testing that went well beyond the industry standard. This is a document from 1978 that talks about the way we were testing our talc, and talks about exceeding industry standards.

J4-1, you're going to hear was the industry standard of how to test. Two microscopes were used, x-ray defraction and polarized light microscopy. Since about the late '60s, early '70s, we went beyond that for all of the talc that we sold, and we use the most sensitive methodology, transmission electron microscopy. And even though our suppliers were certifying the talc was asbestos-free, the talc was of highest quality, we hired the best lab in the country. And even plaintiff's experts will agree with that. This is Walter McCrone. He and his wife Lucy owned McCrone Laboratories, and everyone on both sides of the aisle are going to agree this was the best microscopy shop available during the '70s, '80s, and '90s. This is the shop when historians wanted to find out if Napoleon was poisoned with arsenic, they sent it to Walter McCrone to look at under a microscope. Same thing with Beethoven and lead

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poisoning.

He is the published leader in the field, and his shop was testing our talc according to our specifications to make sure it was safe.

One of the things you're going to hear, I suspect, is a lot about asbestos in this case. And one of the things that is going to be clear is that asbestos is everywhere. We are all exposed to asbestos. It is in the air, it was building our schools, building our homes. And that's something that the FDA has considered over the years -- let me just get my clicker to work.

That's one of the things that the FDA has considered over the years. So when the FDA was looking into this issue back in 1996 and they denied the citizen's petition, they said, We don't think there is asbestos in cosmetic talc. We're going to run something called a worst-case estimate of exposure. We're going to assume that there is 0.1 percent asbestos in cosmetic talc. Would that present a health risk to the consumer?

And they did a whole study on it and they concluded everyone at 0.1 percent, which is a ton more than is even being alleged in this case,

0.1 percent -- no health hazard because it would it

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would be less than what we're exposed to just walking around the United States of America where asbestos was used to build our country for many, many years.

So you are going to see the documents that assure there was no asbestos, and even what they're alleging in this case -- this is Dr. Rigler, he's going to come in and say, on average, there was 0.0001 percent. Even if you take them at their word, that is a hundred times less than what the FDA said was not a health hazard.

And we are going to talk, I imagine, quite a lot about the contamination event that the FDA picked up in 2019. But even if you take what they found in that one lot, 0.000002 percent, 5,000 times lower than what the FDA said was not a health hazard.

And this is a good thing. The fact that the FDA was able to pick up three fibers in one line -- in one sample, showed that their program of oversight, their program of testing and monitoring cosmetic talc issues was working. They were testing from the most sensitive methods and they were able to pick out what turned out to be a contaminated sample.

And you are going to get to see the 155 tests that Johnson & Johnson did to confirm that that bottle where they found three fibers in was

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contaminated.

We had a statistician tell us you would have to do 23 tests of the bottle before, the bottle after, the retained lot, to assure yourself that this was contamination and not the talc. That wasn't enough for us. We did 155. 155 tests, no asbestos detected, to assure that the product was safe and that it didn't have asbestos.

So we will talk about, in this case, some of that testing that was done over the years, but I want to just leave you with this. Mr. Sugarman has some of the bottles that he claims Dr. Seskin used. he produced them in this lawsuit. And as we talked about at the beginning, the plaintiffs in this lawsuit, they have the burden of proof. They sued They have the burden of proving to you what they say is true.

And you are going to be surprised, I think, to learn they didn't test a single one of those bottles. They have the bottles that they claim she used, that they sued us over, that they claim have asbestos, they have an expert who tests bottles for asbestos and they didn't give them to us. They didn't test them.

You will have to sort through that and figure

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out why. If it is true that they have asbestos, why didn't he test them? And then you are going to hear in terms of the tissue, the pathology that exists of Marilyn Seskin's surgeries where there is actual tissue, they have an expert who digests that tissue to look for asbestos. He didn't do it here.

They have an expert who can look at pathology under a proper microscope and see if there is talc or not. They didn't give it to the expert who uses the microscope who can do that test.

You are going to see that even the lower-powered microscope that they used to identify what Counsel called a sparkly particle that could be dirt, could be sand, could be anything, even that, even if what he was identifying was talc, there is no reaction in the tissue. You are going to see there is no inflammatory response. There is nothing to suggest that whatever that particle is, that it could possibly be causing cancer through an inflammatory response.

So some of the things you are going to have to sort through as the evidence comes to you in this case is if the plaintiffs have the burden of proof, if the bottles of the tissue are available, why was none of this done?

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I would submit to you all that the evidence is going to be overwhelming, the scientific evidence is going to be overwhelming that this product is safe and does not cause ovarian cancer or primary peritoneal cancer.

I would ask that you keep an open mind as you see snippets of documents come to you because I suspect they are going to be shown in a way they were shown this morning, in a misleading way to suggest to you something that is not true. So keep an open mind.

The way it works, we come second in the case, and we very much look forward to putting on this case and proving to you this product is safe.

Thank you all so much for your attention. I appreciate it.

THE COURT: All right. Thank you.

Ladies and gentlemen, your option. We can take lunch now, or we can take lunch at 1 o'clock.

Now? All right. We will be in recess until 1 o'clock.

Remember, you cannot discuss the case amongst yourselves or with anyone else. No independent research. And the parties are going to avoid you. And if there is any reason anyone should attempt to

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1	communicate with you about the case, please bring
2	that to my attention as soon as you possibly can.
3	Enjoy your lunch.
4	(Jurors exited the courtroom.)
5	THE COURT: All right. Anything anyone wants
6	to bring to my attention?
7	Enjoy your lunch. See you back here at 1
8	o'clock.
9	(Thereupon, the proceedings concluded for the
10	morning at 12:13 p.m., and will continue in Volume
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Page 573 1 CERTIFICATE 2. 3 I, ELIZABETH CORDOBA, Registered Merit 4 Reporter, Certified Realtime Reporter, Florida 5 Professional Reporter, certify that I was authorized and 6 did stenographically report the foregoing proceedings and 7 that this transcript, pages 432 through 573, is a true record of the proceedings before the Court. 8 I further certify that I am not a relative, 9 10 employee, attorney, or counsel for any of the parties nor am I a relative or employee of any of the parties' 11 12 attorney or counsel connected with the action, nor am I 13 financially interested in the action. 14 Dated this February 14, 2024. 15 16 17 18 19 & condoba 20 ELIZABETH CORDOBA Registered Merit Reporter 21 Certified Realtime Reporter Florida Professional Reporter 22 23 24 25

Page 574 IN THE CIRCUIT COURT OF THE 11th JUDICIAL CIRCUIT 1 IN AND FOR MIAMI-DADE COUNTY, FLORIDA 2. CIRCUIT CIVIL DIVISION 3 CASE NO.: 2019-017627-CA-01 4 5 ROBERT A. SUGARMAN, Individually and as Personal Representative of the Estate of MARILYN WENDY SESKIN, 6 7 Plaintiff, 8 v. 9 JOHNSON & JOHNSON, JOHNSON & JOHNSON CONSUMER, INC., f/k/a JOHNSON & JOHNSON, CONSUMER COMPANIES, INC., and PUBLIX 10 SUPER MARKETS, INC., 11 Defendants. 12 13 14 15 Volume IV 16 Pages 574 - 733 17 18 Miami-Dade County Courthouse 19 73 West Flagler Street Miami, Florida 33130 20 Tuesday, February 13, 2024 1:07 p.m. - 4:40 p.m. 2.1 This cause came on for trial before the 2.2 Honorable William Thomas, Circuit Court Judge, taken 23 by Christine Savoureux-Mariner, FPR and Notary 24 2.5 Public in and for the State of Florida at Large.

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(Trial proceedings continued at 1:07 p.m.)

MS. BROWN: Your Honor, can we raise one quick issue with the Court, please.

THE COURT: Absolutely.

MS. BROWN: Thank you. There is something that was subject to a motion in limine in the proposed slide deck for this witness and Ms. Scott was going to raise it with the Court, with your permission.

THE COURT: Let's go, quickly.

MS. SCOTT: Yes, of course, Your Honor. So motion in limine number 20, we're seeking to exclude warnings on talc products that were not manufactured by J&J. It came up because we saw that in Ms. Plunkett's direct sides. We also have the demonstrative here. Those warnings on other manufacturers' talc products is not relevant to this case. That involves Ms. Seskin's use of Johnson & Johnson baby powder.

No other -- the allegation is she didn't use any other baby powder, and so whatever warnings are on other products aren't relevant or probative. I think what they are going to try to say is that these warnings on other people's products go to establishing some sort of industry standard, but

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these warnings came after this talc litigation started and is responsive to that, rather than setting some industry standard that J&J was allegedly supposed to follow back in time.

MS. O'DELL: Your Honor, these manufacturers began to warn in 2017. These bottles are from 2017 when Ms. Seskin was using talcum powder. They show that the industry standard, people were acknowledging that you should warn -- manufacturers were warning of the risk.

There was discussion yesterday about other manufacturers, and so we think it's relevant to show that there were other manufacturers manufacturing body powder with talc that recognized the standard was, if there is a hazard, you shall warn and they did. And they have a specific ovarian cancer warning.

And this is in 2017 and these are bottles that Dr. Plunkett found on her own and she is — they're relevant to you should have warned, they're relevant to the industry standard, they're relevant to how the FDA regulatory standard is applied. So we feel like they are very probative and they should be admitted, just for demonstrative purposes, to juxtapose the J&J baby powder label

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Page 580 1 with these labels at the same time period. MS. SCOTT: Your Honor, as Ms. O'Dell 3 mentioned, these are from 2017, just after Ms. Seskin was diagnosed with her cancer. And in 4 5 addition, I mean, we have actually a website printout from one of the manufacturers that says we 6 7 take women's health -- basically they're saying there is no scientific proof to support this, but 8 9 we are just putting this on here for an abundance 10 of caution. 11 Why? Because now Johnson & Johnson, that's 12 been three years later, three years of litigation, 13 Johnson & Johnson has been sued so now we are going 14 to put a warning. That's not probative. 15 THE COURT: Did any other company making talc, 16 did they put any warnings on their products? 17 MS. SCOTT: As to ovarian cancer? 18 THE COURT: Okay. 19 Not until after these lawsuits MS. SCOTT: were filed. 2.0 When was the first lawsuit filed? 21 THE COURT: 2014, Your Honor. 2.2 MS. SCOTT: 2.3 THE COURT: So since 2014, there are other 24 companies that have put labels on their -- warning

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labels on their product?

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MS. SCOTT: Years later. I mean, the example that we have here is going to be 2017.

THE COURT: But why can't they ask the question whether or not the Johnson & Johnson was aware of the fact that there were other companies who made talc who put labels on the product?

MS. SCOTT: Because one, Your Honor, it's irrelevant. Again, to the extent they want to put this in for industry standard, the relevant time period is -- this is outside of the relevant time period.

THE COURT: No, she didn't get cancer in 2014.

MS. SCOTT: She got it in 2016, but these specific products that they want to show is from 2017.

THE COURT: I'm not sure whether or not you should show the product, but I think you can ask the question. I don't know if you can compare the label from 2017 to, I guess, Johnson & Johnson's label, but I don't see the problem with you asking the question: Did other companies, in 2014 or prior to your client, whenever your client was diagnosed, did other companies put labels on their -- other companies that manufactured talc, did they put labels? They did. And your person

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can say they did.

MS. O'DELL: Your Honor, we can definitely do that. We think a picture is always worth a thousand words and so -- but I'll ask her that question. She will say specifically for ovarian cancer and just so the --

THE COURT: She can say that too. I don't have any problem with her saying that.

MS. O'DELL: So the Court is aware, this is during a time period when Ms. Seskin was continuing to use the product, and I think that's relevant. The other aspect as well is Ms. Scott has suggested that the only thing that was going on in the world was litigation, that's actually not true. There was a lot of scientific evidence.

THE COURT: So the objection is sustained in part and overruled in part. I'm not going to allow you to use the demonstrative and show the label, but I am going to allow your expert to testify, if your expert can, that during the time that

Ms. Seskin used the product, other companies that made talc put warning labels on their product and you can even enlist the testimony that those warning labels included warnings as it relates to ovarian cancer.

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MS. O'DELL: Thank you, Your Honor.

MS. SCOTT: One point just for the record, Your Honor. This is also highly prejudicial. would lead the jury to have the inference that just because other folks put labels on their products for reasons completely unrelated to the science, that Johnson & Johnson somehow fell below some sort of standard. And it would require us to engage in a sideshow that we are engaging in now, which is what motivated those other manufacturers to put those labels on their product.

THE COURT: You can ask that question. don't know what you all keep saying. All of your favorite words is "sideshow." I don't know if that's code for something, but -- okay. The jury is coming in.

MS. SCOTT: Thank you, Your Honor.

THE COURT: Mr. Rios is saying he's having an issue with his employer. They are not going to pay him.

(The jury enters the courtroom.)

THE COURT: For the record, all of the jurors are present making their way to their seats. the parties are present. All right.

All right. Plaintiff, call your first

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1	witness.
2	MS. O'DELL: Your Honor, we call Dr. Laura
3	Plunkett.
4	Thereupon:
5	DR. LAURA PLUNKETT, PH.D., DABT
6	Was called as a witness and, having been first
7	duly sworn and responding "Yes, I do," was examined and
8	testified as follows:
9	THE COURT: You can have a seat. Give us your
10	full name, spell your last name for the record,
11	please.
12	THE WITNESS: My name is Laura Massey Plunkett
13	L-A-U-R-A, M-A-S-S-E-Y, P-L-U-N-K-E-T-T.
14	THE COURT: You may inquire.
15	MS. O'DELL: Thank you, Your Honor. Good
16	afternoon everyone.
17	DIRECT EXAMINATION
18	BY MS. O'DELL:
19	Q Good afternoon, Dr. Plunkett. Would you
20	please introduce yourself to the jury.
21	A Sure. My name is Laura Massey Plunkett. I
22	live in Houston, Texas. I'm a consultant. I own my own
23	company and I'm here to talk about issues in this case.
24	Q Thank you very much. I'll let you get settled
25	there. Since you're getting your notebook set, I'll

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make sure you're in good shape.

Would you please just tell us a little bit about your professional background. First, are you a pharmacologist?

- A Yes, I have a doctoral degree in pharmacology from the University of Georgia.
 - O And what are your other years of expertise?
 - A So I'm also Board certified in toxicology -THE COURT: I need everything off the screen
 unless it's already in evidence. You may proceed.

THE WITNESS: I'm Board certified in toxicology and have been since 1993. I'm also a registered patent agent and I practice in the areas of pharmacology, which we'll talk about in just a minute, toxicology, intellectual property, which is my patent work, and also I deal with regulatory issues with my clients.

BY MS. O'DELL:

Q So as we begin, Dr. Plunkett, would you mind just describing and explaining what pharmacology is.

A Sure. So in simple terms, pharmacology is what drugs or chemicals do to the body. So most of us are familiar with drug products we take at the pharmacy and we take them for a purpose, and that purpose is what pharmacologists study; what is it that the drug can do

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to your body once you ingest it.

Q And you mentioned you're a toxicologist. Would you describe what toxicology is and what that involves.

A So toxicology is very similar. It's a study of what chemicals or drugs do to the body, but it's looking at the undesired or adverse, or we'll use the word toxic, effects; the things you don't want to happen or that it could be harmful to your health.

MS. O'DELL: Your Honor, may I put up a slide that summarizes Dr. Plunkett's qualifications?

It's not evidence, just for demonstrative purposes.

THE COURT: No.

BY MS. O'DELL:

- Q Are you Board certified?
- 16 A I am. I just said --
 - Q I'm sorry, forgive me if you just said that.

And let me ask you this: Do you have expertise in regulatory matters, and would you explain to us what that involves?

A Sure. Yes, I do. So in the federal government here in the U.S., the different agencies that are responsible for oversight of different kinds of products that we're exposed to every day have a set of rules called regulations, and what I do is I work with

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clients that may be developing a product that is regulated as a drug or a medical device, food or cosmetic.

I also work -- and that's through the FDA, and I assist them in understanding what the regulations are, what are the rules for developing the product, how can I develop my product and actually make it to the marketplace, what do I have to do, what kind of information do I have to provide to the FDA, the Food and Drug Administration, to obtain that approval process.

I also worked with companies in another regulatory agency called the Environmental Protection Agency -- we may refer to it today as the EPA -- and they regulate a different class of products. regulate things such as household chemicals, industrial chemicals, things that -- plastics and things like that that make a variety of products we're exposed to.

They also regulate a group of products called pesticides, which are products that are used in the agriculture industry, to ensure that we can feed the world with the safe food supply based upon the needs that we have in order to feed the population.

But there's rules around that. You know, pesticides can have harmful effects and we have to

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follow the rules in order to get those products onto the market.

Okay. Would you describe for us what we've 0 asked you to do in this case. When we reached out to you and asked you to participate in this case, what was the role or the job we asked you to consider?

Sure. So I was asked to look at the substances that are in Johnson's baby powder and determine whether or not there were any substances in the powder that could cause a harm to health, to a human, injure a human body in some way.

And then I was additionally asked to look at the substances in that product and that issue related to the harm that could be produced in light of the regulations that exist, and how a cosmetic company must -- what types of rules are around that they need to worry about when they're putting a product on the market.

So how does that profile of the cosmetic ingredients or the product itself, the baby powder, fit into that regulatory standards or rules that exist here in the U.S.

Okay. And Dr. Plunkett, you mentioned just 0 briefly something. I would like for you to just describe your educational background and how it applies

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to this case.

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A Sure. So my degree -- well, my first

Bachelor's degree was in zoology. Sounds like a little

odd linked to what I do today, but zoology is actually

the study of physiological systems in a variety of

organisms, all the way from a snail up to a mammal.

And so it was a very useful degree for me then when I went to extend my training into pharmacology. I was always interested in the way that human health can be affected by exposures to things, such as a drug, and that's what pharmacology is, understanding when you take a drug, what happens to your body, how can you develop products that actually treat disease. So it was a good fit for me when I was interested in doing further study beyond my Bachelor's degree.

And then I did a post-doctoral training at the National Institute of Health, and there I extended my training and went from something that I call a whole animal pharmacologist -- I used to be very interested in looking at the whole organism and understanding how the drug affects the whole organism, the live organism, and I extended my work to be looking at the cellular level and understanding how it is that drug exposures or chemical exposures are affecting systems within your body and how those systems in your body within the cell

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are responsible for the way that the drug produces the desired effect or the chemical can produce the undesired effect, depending on what it is that you're trying to study.

And toxicology is an extension of what I did because the original work that I did on my training, I was actually looking at the toxicity of a drug in humans. So it was a general flow for me to move into more work that didn't just look at understanding how drugs may produce their beneficial effects or chemicals can produce effects that you want them to produce, but also looking at when it becomes harmful and understanding the full spectrum of the kinds of effects you can get from exposure to either a drug or a chemical in your environment.

- Q And those chemicals could be in drugs or they could be in cosmetics, for example; is that fair?
 - A Yes, that's exactly right.
- Q So would you tell us about your work experience.

A So I started out, after I did my post-doc at NHI, I took a faculty position at the University of Arkansas in the medical school, and I was an assistant professor in the pharmacology department and I had accepted appointment to the toxicology department. And

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there, I did what most academic scientists do; I did research in a laboratory in areas that I was interested in.

I also taught medical students in the second There's a course in pharmacology they had to I taught graduate students in the laboratory and also in courses at the university. And I was there for about a little over three years.

And then after that, my family moved to the Washington, D.C. area. And in the D.C. area, I kind of switched my career. Went from an academic career into what I do now, I just did it for a company. I worked for a company in D.C. originally called Environ, and that's where I became involved in consulting projects and actually got into the regulation of products and understanding how my background in pharmacology and toxicology fit into the way that the different federal agencies set the rules for what products can be on the market.

Okay. Have you published in what's called the 0 peer-reviewed literature? And as you answer that question, would you mind explaining what it means to have peer-reviewed literature.

Α Sure. Scientists, especially in academics, are required to -- are expected, actually -- to take the

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work they do and make it available for others so they understand what did I find and I'm going to explain it to my colleagues.

And you do that in medical journals or scientific journals. And in order to get the work put into those journals, you have to submit your work for review by others in your field. They are called -- that's what the peer-review process is.

So I published a number of articles in peer-reviewed journal and it's a typical process that a scientist -- I still do that today just because I'm not working in a lab. There are things I do and there's journals that I submit articles to that are appropriate for the kinds of analyses in the work I do today outside of actually working in a laboratory.

Q And what are some of the topics that you published on?

A So over the years, I've published on the issues of cancer risk, looking at some of the issues related to why it is that cancer may have developed in an animal. I've published on pharmacology, basic studies I did in my laboratory at the University of Arkansas on a variety of different kinds of drug exposures.

I published on pharmacology -- pharmacological

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effects or the way that chemicals change cellular mechanisms within drugs. I've also published in the area of toxicology generally looking at adverse effects that could be produced by chemicals and talking about how to put those toxic effects into the context of what could be safe or not for a human being to be exposed to.

I've also published in the areas of regulatory policy or regulatory standards as well for different kinds of consumer products.

- Are you an expert in the area of government regulation as it relates to cosmetics and pharmaceuticals to toxicology, pharmacology, and cariogenicity?
 - Yes, I am. Α
 - 0 Who are you employed by now?
- So I now own my own company. It's called А BioPolicy Solutions, and this company has been in existence since 2020.
- And what type of work do you do as a part of 0 BioPolicy Solutions?

So it's the same kind of work I've been doing since I joined Environ. Since I joined Environ and I've had two other companies I had before this. I've had different business partners, so we've changed the name over the years.

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I do three basic practices. As I said, I'm a registered patent agent. So since 1997, when I started that kind of work on my own, I work with inventors, mostly in the university systems, and I help them get patent protection, so apply for a patent to the U.S. patent and trademark office.

I also work with small companies that are spinning out their first products and do sort of reviews of the landscape of what opportunities are out there to commercialize based on whether they do or don't have a patent protection for their particular products. I also, since I joined Environ, had a lot of experience working with clients in what I call the regulatory space. So variety of different kinds of products that are regulated.

I'm going to focus mainly on the Food and Drug Administration here because that is the regulatory authority that is involved with cosmetics. I have worked on all different kinds of products regulated by the FDA, but particularly in the cosmetics base, since I joined Environ, and I've continued to do that, even to today.

I have worked with cosmetic companies or cosmetic ingredient manufacturers on product safety assessments, on compliance with the regulatory framework

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that exists in the U.S., but also internationally as well because different places in the world regulate these products differently. I've looked at labeling issues for products.

I've looked at marketing and promotional materials because there's certain things you can and can't say depending on the kind of product that you're talking about. And for cosmetics, there's certain things you can and can't say on the labels. You can't make health claims, for example, about a cosmetic product.

I've looked at issues about contamination, whether or not certain contaminants, things that could be harmful in a cosmetic and what the issues would be for exposure through that kind of product.

So it's been a wide range and a wide range of different kinds of ingredients I've looked at, colors, preservatives, what I call penetration enhancers chemicals, that the reason they're in the product is in order to help the ingredients that you want to get through the skin, actually get in deeper into the skin, moisturizing, anti-aging ingredients, ingredients that are called bio-actives, which means that -- there's a lot of cosmetics on the market now that talk about wrinkle reduction, anti-aging, and those are things that

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products?

Page 596 1 actually have pharmacological activity in your skin, but you have to get it into the skin to have that effect 3 occur. 4 So have you provided guidance to cosmetic 0 companies about the ways in which they should comply with FDA regulation? 7 Α Yes, exactly. The clients I've worked with, I have done that. 0 Are you doing that currently with clients? Α Yes, I currently am. Have you done that frequently over your Q 12 25-year career in this -- as part of your work? 13 Α Especially in the last 15 to 18 years, 14 I've done more work than I used to do, I'd say, in the first ten years of my career. At Environ, we did work 16 with the cosmetic industry, but a lot of the work that I 17 have done in this area, in this space, has been more in 18 the last 15 or so years. Okay. You were talking about -- let me ask 0 you this question before I go there: In relation to your work with cosmetics, have you also evaluated the 22 presence and the effects of heavy metals in cosmetic

Α Yes, I have. When I mentioned contaminants, heavy metal is something that can be considered a

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contaminant, something that could hurt you, and so you don't want that in the cosmetic product, particularly if you think the heavy metal has some way it can penetrate through the skin and actually get into your body.

Q What would you estimate your percentage of time, particularly over the last 10 to 15 years, has been spent working in relation to the cosmetics base?

A As I said before, I don't have an exact number but it's probably about 10 to 15 percent of the time that I have spent with my regulatory clients.

Q Let me take you back. You mentioned Environ, which is a company you worked for earlier in your career.

What type of work did you do for Environ, specifically some of the chemicals or compounds that you looked at as a part of your work there?

A Sure. So there's two that I worked on at Environ that are actually relevant to the issues in this particular case.

When I was at Environ, we did a project looking at talc as a dusting product for condoms, and that work was looking at -- was spurred -- we were working for a condom manufacturer and the work was spurred by the questions that would be raised about whether or not there was a safety concern if talc was on

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the surface of a condom for women that would be exposed through the vagina when the condom was touching the surfaces internally. There was some studies or some issues that had been raised in issues about local irritation and inflammation, but also it had been discussed about a risk of ovarian cancer at that time as well with talc exposure through this route.

And then I also worked at Environ on asbestos. So there was a couple of projects we had that were related to different industries and looking at exposure mainly through inhalation pathways, but looking at the issue of whether or not the worker injuries were consistent with what the literature would indicate could happen when you were exposed to asbestos.

So we were doing a risk assessment based on exposure levels and what types of toxic effects asbestos can cause.

Okay. I want to take you back a moment to your work in relation to evaluating the potential risk of talc being used on a condo.

As a part of your work, did you recommend that the condom industry or those manufacturers stop using talc on condoms?

Α My conclusion was that -- and others that were working with me on the product -- was that talc could

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injure tissue and that it could be harmful. And it was eventually -- well, the condom manufacture industry eventually removed talc as a dusting powder from their products.

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But that was the conclusions that I reached and the individuals at my company that were looking at this issue, talc could injure tissue could be toxic to tissue when there was an internal exposure, such as on the surface of a condom.

And as a part of your work, do you interact routinely -- and you mentioned some of these -- with government agencies such as the FDA and others that regulate chemicals and other compounds?

In the work I do with my regulatory Α Yes. clients, it requires me, at different times, to actually have direct discussions with FDA, meetings. I mean, I had a meeting earlier last week with FDA group about one of my clients and the issues that we're dealing with in order to gain an authorization from the FDA for a new type of food ingredient.

In addition to your work as a patent agent and what you've described in terms of consulting with manufacturers, do you also do litigation work?

Α I do.

Q Obviously, you're here.

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A And I didn't mean to not mention that. I think you asked me a question about --

Q This is typical. I probably asked not the best question, but you gave a good answer. So please tell us about your litigation work.

A So that's the third area in my practice. So I work -- have been working, since I joined Environ, on litigation cases involving injuries of humans typically to certain kinds of exposures, chemicals or products, drugs, medical device -- things that are in medical devices, different chemicals, different failures of a medical device. I've looked at food issues; is there a safety concern with certain kinds of contaminants found in a food product in a litigation context. And I've continued to do that over the years.

I do do product liability, that's what I would call this litigation, and I've worked with cosmetics, medical devices, drugs, and dietary supplements in the litigation space.

Q What percentage of your professional time is devoted to litigation?

A So it depends on the month, but the average for me is about a third of my time is spent in litigation. It just depends on one month to six-month period. I did very little during the pandemic because

Page 601 1 there was little active litigation going on. 2 MS. O'DELL: Your Honor, Dr. Plunkett has 3 testified to all the elements on the slide. Do you mind if I display it for the jury? 4 5 THE COURT: No. BY MS. O'DELL: 6 7 Dr. Plunkett, is that an accurate summary of 8 what you've been testifying to as part of your 9 background and qualifications? 10 Α Yes, I believe so. You mentioned your litigation work and the 11 0 12 percentage of time that you do that. Have you been 13 approached by opportunities to participate in litigation and decline them? 14 15 Α Yes. That's the way I look at these cases, 16 exactly. 17 0 How do you make the decision on whether you 18 get involved in a case or not? 19 Α So if I get a call or contact from somebody about a new litigation area, something that I've not 2.0 done before or even a new case that I've not looked at 21 2.2 before in same area, I ask for some facts. If it's 2.3 something that I'm familiar with, I may be able to go 24 back and look at things I've already collected, or I'll 25 collect information, do a several-hour review, ask the

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lawyer to potentially give me some information about what the case involves, and then I make a decision based on whether or not I think I can support the issues in the case or not. So I do turn down cases on a regular basis.

So you've testified -- shared with the jury what we asked you to do in this case. But once you agreed to consider working with us, what methodology did you employ? What did you do to inform your opinions in this case?

So since this case involves both issues related to what I call the science of toxicology and human health injury, as well as regulatory issues as well, I did a broad search of the literature on the issues that I was asked to address. So I looked for -went through the scientific literature looking for information related to the toxic effects or the safety issues related to talcum powder and the different ingredients. I think we are going to get into that later, so I won't go into it.

But there's specific individual substances that are found within the talcum powder bottle, so I was looking across that literature. In this particular case, this is a product that's been on the market for such a long time, that literature searching and look

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took me back to the 1920s with some literature on the safety of talc. But that's -- a lot of times that isn't the case. I can't go back that that far, but this one I could.

And the regulatory part of the case, what's important is often to understand not only what could be known by looking at the scientific literature, but you need to understand what does the company know about the safety of the product or what kind of information did the company have when they made a decision to put a product on the market. So that kind of information is not public. I can't typically go and find that by doing a search in the medical literature or even an internet search.

So that typically requires me to do what I did in this case, which is to look at documents that are produced by the company as part of a process called discovery where the company makes documents that are from their company available for somebody like me to look at. In this case -- and this isn't always the case, but in this case, I was given access to a very large database of documents that had been turned over by the defendant, and I actually went through them on my own looking for things related to the safety of talc and the different constituents, looking at discussions, for

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example, asbestos as an issue, fibers are an issue. looked for those kinds of documents in their internal discovery.

I also looked at deposition testimony of corporate witnesses to understand what the company said about their history of how they handled this product over time, you know, questions that may have been asked internally and understanding how the company handled those issues. I looked at the FDA website to understand if there was anything the FDA has said about these particular products over time.

And then I looked within the internal company documents as well to look at their -- any interactions they had had with either the Food and Drug Administration or other regulatory authorities around the world about either the safety of their product or some of the constituents and substances that are associated with harm that may exist in their product.

So there were thousands of documents that I looked at over time and I've been working in this area for about six years, so it's not that I did it all in the last two months. Over the years, I've looked at those thousands of documents and hundreds and hundreds of pieces of scientific literature.

Q Dr. Plunkett, do you recall approximately how

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many documents you -- company documents you looked at to reach your opinions in this case?

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Α So I believe it's greater than 5,000 at this point when we counted it up, based on the number of documents that have been used and are in boxes.

Okay. Let me ask you a couple other questions about this area.

Did you perform a systematic review? Did you look at everything and analyze it in a systematic approach?

Yes, I do. As a scientist, when I'm trying to А answer a question about whether or not I believe, for example, that something can cause harm or there can be a safety concern, I don't just look for articles that say it's not safe, I look at across all the information I can find that is relevant to the issue of can it cause a toxic effect, can it cause harm to an individual. So it is looking for evidence that exists or information that exists across the universe of studies that have been done.

And I'm not just interested in studies that are in people or in humans, if they exist, but I'm interested in animal studies because they tell me a lot about how actually injury can occur. And then I'm also interested in studies that might have been done in a

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test tube or petri dish, cell studies. I talked about having training in that in the past. Those are really informative to understand why it is, for example, that you might have people saying talc, in this particular study, shows a relationship to cancer.

Why could that be? And so you ask those questions as a toxicologist, so you're looking at mechanism, understanding what are the underpinnings for why it makes sense that talcum powder could be associated with cancer.

- Q Have you used the same care in your work for this case that you use outside of litigation?
 - A Yes, that's correct.
- Q And approximately how many hours have you spent on this litigation?
- A Over the six years, I think it's over 1,400 hours now.
 - Q And what's your rate per hour?
 - A It's \$300 an hour.

MS. O'DELL: Your Honor, at this time I would offer Dr. Laura Plunkett as an expert in the areas of pharmacology, toxicology, FDA cosmetic regulatory framework, and cosmetic industry standards.

MS. BROWN: Your Honor, consistent with our

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Page 607 1 earlier objections, we would object to the FDA regulatory framework and industry standards. 3 Next question. THE COURT: 4 BY MS. O'DELL: 5 Dr. Plunkett, I'm going to ask if you would summarize your opinions in this case. And have you 6 prepared a slide that summarizes your opinions? 7 8 Α Yes, I did. 9 MS. O'DELL: Your Honor, may I have permission 10 to put the slide on the screen? 11 THE COURT: You may. 12 BY MS. O'DELL: 13 0 Please summarize your opinions that you plan to offer in this case. 14 15 Α Sure. When I told you what it is that I was 16 asked to do, this first kind of summarizes that. 17 looked across the information that's available and I 18 formed the opinion that asbestos, fibrous talc, and 19 platy talc in Johnson's baby powder create a significant human health hazard from when the product is used in the 2.0 21 genital area. 2.2 The second opinion I formed has to do with 2.3 that historical look across the literature, and based 24 upon what I have seen since the 1960s, Johnson & Johnson 25 failed to warn consumers of ovarian cancer risks based

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on what information existed starting in the 1960s.

The third area is also related again to that what's in the bottle. It's my opinion that Johnson & Johnson's failure to list these toxins, asbestos and fibrous talc, for example, on its baby powder label is consistent with FDA's definition -- I think we are going to define these later -- of misbranded or an adulterated product.

I've also formed the opinion that the Johnson's baby powder, when you apply it to the genital area, can migrate. So it can move from outside the body to inside the body going into the ovaries and the peritoneal cavity causing inflammation as the mechanism leading to cancer.

I've also -- again, in looking at the literature as well the internal company documents that I mentioned, it's my opinion that cornstarch is a safer alternative to talc-based Johnson's baby powder. And the last opinion is that Johnson & Johnson failed to protect consumers as a responsibility company looking at my experience with the industry while interacting with the regulatory agencies. And again, we are going to talk a little bit about the Food and Drug Administration.

The other acronym here, NTP, stands for the

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National Toxicology Program, the other agency here in the U.S., and then also Health Canada.

Q Do you hold these opinions to a reasonable degree of scientific certainty?

A I do.

Q Let's switch and talk about the regulatory environment or the rules of the road for cosmetics specifically, and maybe I should start there. The jury has heard from counsel this morning and a little in voir dire about Johnson's baby powder, but under the U.S. regulatory scheme, what type of product is Johnson's baby powder?

A It's cosmetic.

Q And would you please define what a cosmetic is under the FDA definition?

A So the FDA, for any product it regulates, actually has a specific definition. So I'm going to read that here just because it's important to understand what the FDA calls it.

A cosmetic is an article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for the purposes of cleansing, beautifying, promoting attractiveness, or altering the appearance.

So I think these are the kinds of things that

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Page 610 all of us probably understand if you go to the pharmacy 1 2 and look at in the cosmetic aisle, that's the kinds of 3 products you'll see. By definition, does that mean that a cosmetic 4 does not have a medical benefit? 5 6 Yes, that's correct. Cosmetics are not being 7 marketed, they are also not regulated as a product that has a benefit. 8 9 And you mentioned the Food and Drug 0 10 Administration and their responsibility over cosmetics, 11 so let's talk about that. You know, what is their 12 authority to regulate cosmetics and have you prepared 13 slide that will help explain how they regulate? 14 Yes, I did prepare a slide because I think Α 15 it's important to understand the details. 16 MS. O'DELL: May I have permission? 17 THE COURT: If there's no objection. 18 MS. BROWN: No objection. 19 BY MS. O'DELL: 20 So let me ask that again. Would you please 0 21 explain what the FDA's authority is or is not over 2.2 cosmetics. 23 Α So unlike most of the products that FDA as oversight of, such as drugs and medical devices, for 24

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example, FDA has no responsibility for actually saying

Page 611 1 or developing the information to show that the product It's the company who markets the product that, is safe. 3 before it puts it on the market, must ensure that the product is safe. And it's all on them. They have the 4 5 legal responsibility to ensure that the products they market are safe. 6 7 Have you prepared a slide that would compare 8 the FDA's responsibilities versus a company's 9 responsibility in marketing a product? Yes, I have. 10 Α MS. BROWN: Your Honor, I would just object to 11 12 the reading of the slides. I think counsel --13 THE COURT: Sustained. 14 BY MS. O'DELL: 15 0 Without reading the slide, Dr. Plunkett, please explain what a company's responsibility is versus 16 17 what the FDA's responsibility is. 18 MS. BROWN: Your Honor, can we take the slide 19 down? 2.0 THE COURT: Remove the slide, please. 21 THE WITNESS: Sure. That's fine. 2.2 As I said, the company is responsible for 2.3 ensuring the product is safe before it's marketed. 24 Unlike other products that exist that the FDA 25 regulates, there is no premarket process for

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review. So it's the company that must do that safety assessment on its own and they market their product. It is only after the product enters the market that FDA has specific responsibilities that it is then going to undertake.

So that means that it's the company that does the initial safety assessment, chooses their ingredients based on the safety that they have to define on their own and develop on their own. They are responsible for doing any testing. If, for example, they choose to put an ingredient in their product and it doesn't have a basis of information to show that it's safe, they are responsible for doing testing to make sure that it is safe.

They are responsible for developing the label for the product, which will tell you what is in it, so the ingredients. They are responsible for listing those ingredients on the label. They are responsible for the labeling on the product and putting information that truthfully tells what is in the bottle and who makes the product.

But it is also responsible for putting other information on the label that may give the consumer information to understand how to use the product safely because, again, it's all about safety for

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these particular products.

They are also responsible for making sure that when they manufacture the products, the manufacturing, they do so in a manner that doesn't make the product unsafe. So they have to make sure the facility where the products are produced are clean. They have to have standards for the ingredients that they put in the product.

So again, that's how they can ensure from time to time and bottle to bottle that the product they're selling is, indeed, as safe as it was the date entered the market. And that's another important thing that the companies must do.

They are the ones that are responsible for ensuring the product is safe, even after it is marketed. So they must continue to monitor their products and understand if new scientific information comes out that raises questions about safety. And they have to look again at the safety of their product.

That is their job. The FDA doesn't do any of those things. Those are all the things that the company themselves must do.

And for other product categories, like drugs and devices, things that have medical applications,

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Page 614 1 some of those things are actually done by FDA and certainly FDA is involved with looking at the safety and the use of the products before they are 3 allowed on the market, and that is not the case for 4 5 cosmetics. BY MS. O'DELL: 6 7 Who has the ultimate responsibility for 0 ensuring that a cosmetic product is safe? 8 9 Α It's the company. And that's from the day the 10 product first enters the market throughout the entire 11 time that the product is marketed. It is up to the 12 company to ensure it is safe. 13 0 Does the FDA approve the labels that go on 14 cosmetics? 15 Α No, there is no approval of labels. 16 0 Does the FDA approve the ingredients that go 17 into a cosmetic product? 18 Again, the company chooses their Α 19 ingredients that are put in the product. 2.0 And in terms of the therapeutic benefits, you 21 said there is no therapeutic benefit, by definition, of 2.2 a cosmetic? 2.3 А That's correct. 24 And does that speak into the fact that this is 0 25 the regulatory framework?

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A Yes, that's exactly right. If there was a therapeutic benefit or medical benefit for the use, there is an ability, particularly when FDA looks at these -- say a drug product before it goes on the market, they can make a decision to weigh the risks and the benefits.

So if there is a benefit, for example, if you develop a drug to cure cancer, save lives, that is a benefit that you may be willing to accept a little risk, a little safety issue with the drug because the benefits outweigh the risks.

That doesn't happen with cosmetics. It's all about is it safe because there is no benefit that is being assigned to that particular product.

Q Let's talk about the industry, for example, specifically the industry standard for warning. And what is that standard in relation to the warning that should be on cosmetics?

A So there is a section of the FDA regulations, 740.1 is the number that's assigned to it, if you go to the book called the Code of Federal Regulations and you find it. And it is a regulation that deals with putting -- it's called establishment of a warning statement.

It is the standard or the information that

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tells what it is that you're supposed to do as far as how you judge whether or not a warning needs to go on. What is the level of evidence or the type of information that's needed in order to add a warning to a label of a cosmetic product.

- Okay. And have you prepared a slide that outlines the FDA regulatory standard?
 - Yes, it gives the language of it. Α
- 0 Thank you. And so what is the regulatory standard for having a warning on a cosmetic?

So the standard is very different from a standard, for example, for a drug. Many people have read drug labels, that's why I keep pointing to that. You go to the pharmacy, you'll see a warning section. On the cosmetic product, the standard for putting a warning on the product is the product shall bear a warning whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

So it is may be associated, prevention of a health hazard is the standard that applies to when a warning should go on. It's very different than the standard, for example, for adding a warning to a drug where the standard is not an issue of may be associated, but where you have information that it's more likely than not that there is actually a health hazard

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associated with a product.

Q And once there is an identification of a hazard that may be associated with a product, is the requirement to warn, is it voluntary or is it essentially commanded by the statute?

A So in my experience, based upon working in this industry, this is a mandatory standard for the industry. In other words, you're being -- if you look at the language of the regulation, the product shall bear a warning.

So it is the understanding that it's not you may decide you want to put a warning, but it's giving you a standard for when the warning should be put there. And in my experience, that's what I have seen in terms of the types of warnings that may be added to cosmetics.

Q Is there a requirement that there be a conclusive causal relationship between the product and the potential hazard?

A No, and that's why the language talks about may be associated.

Q And why is that important to have that particular standard?

A Because this is a product that has no benefit.

And so the idea is that, if something has the potential to harm, you want the consumer to understand that that

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risk or that hazard or that potential is there so you can make an informed choice for a product that is not providing you with a benefit.

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Is the language that we see on the screen, 0 that 740.1, that part of the regulation, is that a codification or sort of a written statement of the industry standard?

It was put in place in the 1970s for the Α first time, based upon the standards that existed before that within the industry.

I want to ask you to define a few more terms that are relevant to the regulatory framework. First, is the term -- what is the term misbranded, and can you define that for us, and is there a definition under the regulations?

Yes, there is a definition under the regulations and I made a slide for that as well.

Q Thank you. What's the -- just tell us what the definition of misbranded is.

So misbranding means that the information А that's on the label may be false or misleading. So it's the idea of not providing the consumer with all of the information or putting it into a way that is not an accurate representation of the product, either be it, for example, failing to list ingredients that are there

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when you're required to list all the ingredients on the label that are there, that's one of the labels issues that you have to deal with cosmetic. You are supposed to provide the consumer with what is actually there in the product.

You can also have a misbranding if you have a lack of a warning or safety information when the product is being used, or you could be misbranded if, for example, you fail to give adequate directions for how to properly use the product when you know that a use could be harmful. So, you know, you need look at what information do we know, what does the company know about the product, and then that information then needs to be put onto the bottle when it impacts the safe use of the product by the consumer.

Q What is the regulatory meaning of the term adulterated?

A So adulterated means there is an ingredient or maybe a contaminant even -- and I'm using that word differently because it may be that it is something that is there, intentionally there. It could be something that is unintentionally there which could be a contaminant, and it is known to pose a risk to health, it can injure you, then that product can be deemed adulterated because that ingredient or that contaminant

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is going to have a harm associated with it.

Q All right. Thank you, Dr. Plunkett.

I want to turn our attention to sort of a new topic and focus now on talc, and specifically have you describe what is talc in regard to how it composes Johnson's baby powder.

A Okay.

Q So let me just ask you: What is talc? Would you tell us what it is from a mineral standpoint?

A Sure. First off, you have to understand talc is mined from an earth. It's actually a mineral ore that is found in the earth. It's mined, and then it's processed and you can produce from that mineral ore from the earth a bottle of powder.

So you process it and you get the powder from the earth. So talc is a mineral that comes from the earth that's naturally occurring. It's made of elements of magnesium and silicate, so that's the name magnesium trisilicate.

That's a technical term, but there's a group of chemicals that are generally magnesium silicates, and talc is one of those. And it is the main substance that is in the talcum powder bottle.

Q Okay. Dr. Plunkett, you have a picture on the screen of an open pit mine with a truck and tractor,

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excavator.

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Is that actually a picture from one of the mines that Johnson & Johnson used to source baby powder?

- Α Yes, that's correct.
- And did Johnson & Johnson used to own the mines in the 1960s, '70s, '80s that sourced Johnson's baby powder?

Yes, they used to source their baby powder from their own mines, now they do not. There is different suppliers since the time that they have mined it themselves.

In fact, I think we may see some documents or information -- you'll see a name Imerys, a company. You may see the name Rio Tinto, you may see the name Cypress, but those are all names of talc suppliers to Johnson & Johnson in the time after they were -- or maybe even while they were still mining themselves, but definitely at the time after they were mining themselves.

Okay. And for many years, did other companies own the mines that were actually sourcing the product, but it was the same mines that Johnson & Johnson had owned?

Α Yes, that's exactly right. They turned over to other -- today you even get mining done in other

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countries, so talc can come from other places around the world, like China.

- And what are the names of some of the -- you 0 mentioned Imerys. What are some of the other names of the talc suppliers that have supplied talc for Johnson & Johnson?
- Α So those are the names I gave you, Rio Tinto -- Imerys, Rio Tinto and Cypress I think are three that you may see.
- And have you seen documents in your review that make clear that, at different times, Johnson & Johnson was working with Imerys, for example, in interacting with regulatory agencies regarding the safety of talc?
- Yes, the talc supplier was very involved with the regulatory agencies over time, particularly in the time period I think we are going to discuss somewhere in the '80s, '90s, 2000s for sure.
- And did they work and collaborate together to 0 essentially defend talc as a safe ingredient?
- Yes, they did. They worked through a trade organization, in particular, as well called the Cosmetics, Toiletries, and Fragrances Association, CTFA, both of them were members of that.
 - Q Thank you.

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Have you come to learn that Johnson's baby powder not only contained platy talc but it includes other constituents or other components?

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Α Yes, that's correct. It is not just platy talc, which is one of the terms I think we had a slide on earlier, yes.

- And does it include asbestos? 0
- There's been evidence for the It does. Α presence of asbestos in the product over time, as well as fibers that are called fibrous talc.
- Okay. And have you prepared a slide that sort of helps us understand how asbestos interacts with the body and also what some regulatory agencies have said about asbestos?
- Α Yes, and this was based on the research that I've done.
- Okay. As we talk about asbestos, before we get into the substance, would you mind telling us some of the types of asbestos that are particularly relevant for this case?

So asbestos is a term for a group of different mineral substances in a group. There's six of The ones we are probably going to see mentioned them. here, there's a form called chrysotile asbestos, and that's in a different shape than the other three that we

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may talk about, which are in a fiber form. And that would be tremolite, anthophyllite, and actinolite. they are all asbestos, but they have different shape and feature sizes so they may occur in fibrous form or they may occur in a different form than that, serpentine form a different structure.

And the structure of the shape -- I will try not to use this word, but there's a word scientists sometimes use called morphology, which just means the size and shape of the particles. And they may differ depending upon the form of asbestos that you're talking about.

0 You mentioned you've seen evidence that demonstrates the presence of asbestos in Johnson's baby powder, but just very generally describe the evidence that you've reviewed.

Α Sure. So there is -- over the years from not only the internal company documents, there's information showing testing for the presence of asbestos in either talc and/or Johnson's baby powder.

There has also been published scientific articles that have talked about the presence of asbestos in talc products, including Johnson's baby powder. there has also been government testing that's been done that has shown the presence of asbestos in talcum

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powder.

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Is asbestos toxic to the human tissue? Q

Yes, we've known since, gosh, maybe even Α before the 1930s, but definitely by the 1930s, there was a general recognition in the science literature that asbestos could damage the tissue and cause -- as I listed here -- it causes changes called inflammation, and we are going talk about that, I think, in a little bit, which means it irritates the tissue and actually injures the tissue through a specific process.

It can also damage the DNA within cells, which means it can also lead to and has been shown to lead to changes that are -- cause the cell to change from a normal cell to a cancerous cell. And asbestos itself has been classified or identified by regulatory bodies and regulatory authorities around the world as a known human carcinogen, and that information has been known for decades.

You have on the slide an acronym IARC. What Q is that?

So it's the International Agency for Research Α on Cancer, and it's a body of the World Health It's an agency under the World Health Organization. Organization. It's located in France, and their mission is essentially to study ways to prevent cancer.

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It looks at also -- they also do clinical studies sometimes for cancer treatment. Their issue is focused on cancer and ways to prevent, treat, and one of the things they do is they actually identify or classify chemicals through a peer-review process where they get scientists together to look at evidence about cancer and they classify chemicals based on the risk of cancer into either a known human carcinogen, into a probable human carcinogen, or into a possible human carcinogen.

And there's some compounds they look at that they may call unclassifiable, which means not enough evidence to put them in one of these other categories. And chemicals or compounds that they look at are nominated or put before them because there's been some issue or interest in understanding whether or not there is a reason to provide the scientific community, but also regulatory bodies as well as consumers with the fact that these particular chemicals can be harmful to health specifically related to cancer.

Is IARC considered to be an authoritative body?

Yes, their decisions are referenced or even relied upon by some regulatory authorities when they make decisions on whether to take action on either regulating a chemical, maybe reducing the likelihood

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that people could be exposed to that chemical in some way.

- Have they done a comprehensive review and 0 published a comprehensive review of their evaluation of the evidence in relation to asbestos?
- Yes, they've done it several times, in fact. I think the first one was in 1987 was the first time they looked at asbestos, and I think they've done it at least one other time since then.
- And have you relied on that as an authoritative source in reaching your opinions?
- Α Because of the fact that, when they go Yes. about this process, they do a review that is based upon looking at all of the potential information, not just on human studies, but animal studies, scientific information to bolster why it is it makes sense that this particular compound can cause cancer and they also look at exposure potential, how people may be exposed to it.
- Okay. And is that the type of source that 0 someone in your position, as a toxicologist and pharmacologist, would routinely rely on?
 - Α Yes.
- What is the most recent systematic review that 0 IARC has done on asbestos?

Page 628 1 Α I believe it's 2012. Q Okay. And --3 MS. O'DELL: Your Honor, may I have permission to put the IARC up on the screen? 4 5 THE COURT: Permission to put up what? MS. O'DELL: IARC -- slide about IARC on the 6 7 screen. Go ahead. Any objection? 8 THE COURT: 9 MS. BROWN: No. Thank you, Your Honor. 10 BY MS. O'DELL: So is this a slide that sort of summarizes 11 12 IARC's conclusion about asbestos, Dr. Plunkett? 13 Α Yes, this is the most recent review they did. 14 And what did they conclude? 0 15 Α They concluded that asbestos and its risk, 16 first off, apply to all six types of fibers wherever 17 they were found, and it was interesting because this is 18 the monograph that was trying to make clear when we talk 19 about asbestos what are we talking about in terms of cancer risk. 2.0 21 And then they also, again, found -- they give 2.2 you what they call their overall evaluation, and they say there is sufficient evidence in humans for 2.3 24 cariogenicity of all forms of asbestos no matter what 25 those forms are. And I think I named four of them and

Page 629 1 there's two others listed here as well. They also 2 stated that asbestos causes mesothelioma and cancer of 3 the lung, larynx, and the ovary. 4 Have other agencies evaluated whether asbestos 0 5 can cause ovarian cancer? А 6 Yes. 7 And what is the conclusion of the National Cancer Institute as to whether asbestos can cause 8 9 ovarian cancer? 10 Α They also have concluded that asbestos can 11 cause ovarian cancer. 12 Are you aware of a recent statement by the 13 environmental protection agency regarding asbestos and 14 ovarian cancer? 15 Α Yes. 16 And did you rely on that in reaching your 0 17 opinions in this case? 18 Α Yes, I did. 19 All right. And what did the EPA conclude 0 2.0 about asbestos and ovarian cancer? Again, that asbestos can cause ovarian cancer. 21 2.2 0 And is there consensus in the scientific 2.3 community that asbestos is a cause or can cause ovarian 24 cancer? 25 Α Yes. In my opinion, there is a consensus,

Page 630 1 yes. And the question, Dr. Plunkett: Is there any 3 safe level of asbestos? 4 Α No, there is not. That's what makes it a 5 unique issue and a particularly important human health or hazard issue. 6 7 And have you, you know, gathered some statements by regulatory bodies and others about what 8 9 they've said in regards to whether there's a safe level 10 of asbestos? 11 Α Yes, I have. 12 Have you prepared a slide? Q 13 Α I did. 14 Objection, Your Honor, hearsay. MS. BROWN: 15 THE COURT: Overruled. 16 BY MS. O'DELL: 17 And what has NIOSH said about whether there is 0 18 a safe level of asbestos, Dr. Plunkett? 19 Α So NIOSH, I should probably define that. It's the National Institution for Occupational Safety and 2.0 21 Health, and their goal is to protect workers. And the 2.2 NIOSH has looked at this issue and they've stated that 2.3 evaluation of all of the human data provides evidence 24 for a threshold -- provides no evidence for a safe level 25 or threshold for asbestos exposure. In other words, no

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safe level of asbestos.

Q Let me stop you there. You've got an aspect of this slide that relates to the Food and Drug Administration, let me ask you the question: Who is Susan Mayne?

A She is one of the directors within one of -- I want to say the food agency at FDA. Within FDA, there's different centers and this is one of the centers and she was a director at the time. And she is the center that is responsible for oversight of cosmetics.

So she would be the center director for the food center under which cosmetics sits. Even though they are not a food, that's where they sit in the federal government.

Q And what was the statement she made in regard to whether there's a safe level of asbestos?

A Again, she confirms that there's general agreement among federal agencies in the U.S. and WHO that there is no known safe level of asbestos exposure.

Q Now, as a part of your work in the case, I think you mentioned that you have reviewed or read depositions of corporate representatives of Johnson & Johnson. What have their statements been regarding whether there's a safe level of asbestos?

A Yes, more than one of the Johnson & Johnson

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Page 632 1 corporate representatives have actually testified that there is no safe -- known safe level of asbestos 3 exposure. 4 So, Dr. Plunkett, I want to turn our attention 5 from asbestos specifically to another component or ingredient of Johnson's baby powder that you mentioned 6 7 earlier, and that's fibrous talc. Would you please define fibrous talc. 8 9 When you use that term, what are you talking 10 about? 11 So we've used two terms, platy talc and Α 12 fibrous talc. So those are different shapes and sizes. 13 The way they look actually, if you were to get them 14 under a microscope -- you have to get them under a 15 microscope to see this. 16 Platy talc means that it's in the form of a 17 It looks flat and it has sort of an irregular plate. 18 A fibrous talc means it is presence of fiber, so shape. 19 it's present in a long thin form. So it looks very different. It would be more of a needlelike structure 2.0 21 versus a flat plate structure. 2.2 So fibrous talc is just identifying sort of 2.3 the shape and size, the way it looks, the way it forms is different. It looks different under a microscope. 24

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Did you prepare a slide with pictures of platy

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talc and fibrous talc just to make that -- sort of pictorially make that distinction with what you just described?

A Yeah, because sometimes it's easier to see it than speak to it.

Q Is that what you were referring to, what you were trying to describe?

A Yes, exactly. If you look at the one on the right, you see that thin fiber needlelike structure, that's a talc fiber. On the other side, we have those irregular -- almost look like flakes, that's the platy talc.

- Q And is fibrous talc also known by other terms?
- A Yes, it has been referred in the literature by other ways.
 - O And what are those?
- A It can be called a term called asbestiform talc, which means, again, it is a fiber form of talc. That's probably the other one we're going to see the most frequently, if we talk about documents or we talk about evidence.
 - Q Okay. Would you define asbestiform, please.
- A So asbestiform is, again, just an adjective that's describing the shape, a fibrous shape.
- Asbestiform means it has a shape or a form that makes it

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look like an asbestos fiber, and that's what asbestiform refers to. So asbestiform talc has a shape and size that can look similar to an asbestos fiber, so a fiber form of asbestos.

Even though asbestos and talc actually chemically are different compounds, they occur together often in the ground, in the ore, and so it makes sense that you might find them together when you process talc and you produce a powder from it through that processing. So you can find fibers of talc and you may find fibers that are actually asbestos as well.

So when you use the term asbestiform, that doesn't necessarily equate asbestos, asbestiform can be applied to multiple types of mineral; is that fair?

That's correct. So that's why I have used, in Α my slides, the name fibrous talc and then I've used asbestos separately to show that these are two different distinct substances that have been found in Johnson & Johnson baby powder.

Okay. How does fibrous talc impact or affect 0 human tissue?

Α It has similar activity to asbestos in that it causes these inflammatory changes that injures the tissue through a mechanism that we're going to talk about in a little bit. Actually injures the tissue

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Page 635 1 through causing inflammation. 2 Most of us may recognize inflammation if we see it on our skin, that's where your skin is red, 3 irritated. These are things you can't see because it's 4 internal in your tissue, but it's the same idea. 5 6 Fibrous talc also can damage DNA and it can 7 lead to, through these mechanisms, cancer formation. It's been identified by IARC, as well, as a known human 8 9 carcinogen. 10 In terms of the IARC monograph, as it Okay. 11 refers to fibrous talc, what term did they use to refer 12 to fibrous talc? 13 Α They called it talc-containing asbestiform fibers. 14 15 In the monograph, do they discuss -- do they 0 16 define how talc containing asbestiform fibers could be 17 platy or could be a talc fiber? 18 Yes, they do. That's what, I think, the Α slide -- it's okay to talk about it? 19 20 Read the pertinent information that you're 21 referring to, please. 2.2 Α So first off, the important thing in the monograph was that the conclusions they had reached 23 about asbestos, they are now talking about how those 24

conclusions about fibers would include talc-containing

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asbestiform fibers. And then they describe what that is and they say talc particles are normally plates, like the picture we showed.

But under a microscope, you may also see And they say talc may form true mineral fibers that are asbestiform in habit. So even if you're looking at a plate and you may think it's a fiber, that's not what we're talking about.

We are actually talking about being able to identify, like we did in the picture, a form of talc that actually looks like a fiber.

- And in the monograph, does it conclude that talc containing asbestiform fibers can cause ovarian cancer?
 - Α Yes, it does.
- We talked about asbestos, we're talking about fibrous talc or talc fibers, now let's turn our attention to platy talc. You've described that, you've shown a picture, but in terms of the characteristics of platy talc, how does that interact with the body and how is that different in some respects to a fiber?

Α Sure. So platy talc also can cause inflammatory changes in tissues. So you can get an inflammation in the tissues. It has not been shown to damage DNA in the same way that the fibers can, but it

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also has been reviewed by IARC and has a separate listing or separate classification where platy talc has been identified as a possible human carcinogen. So we have known for the other two constituents and now this one is identified as possible.

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Q Okay. And is one of the reasons for that distinction in the evaluation because of the shape of the mineral?

A Yes. There is evidence and scientific studies that have been done to show that the shape of the mineral affects the way that the tissue reacts to it. So.

The fiber form is more injurious or injures the tissue more readily than the platy form does. So you have to get a higher level of exposure and you get a little different response.

They all three can cause inflammation, but the cancer potency or the ability of the asbestos and the fibrous talc to induce a cancer response can occur at lower levels of exposure.

Q And you mentioned the IARC had concluded that platy talc alone is a possible carcinogen. When did they reach that decision?

A That was in 2006, when they reached it. They had a meeting and it was published in 2010. But yes,

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they reached that conclusion in 2006.

- And so was that information known in 2006? Q
- Yes, it was. Α
- And in response to that announcement by IARC 0 that platy talc or talc not containing asbestiform fibers was a possible carcinogen, what did the talc supplier for Johnson & Johnson do?

They added a statement on their information Α that was sent out with each shipment of talc from the supplier to parties like Johnson & Johnson, people that bought the talc. And it actually told in that document what IARC had found.

So it actually took the conclusions of IARC on this particular compound and talked about how IARC had found -- what IARC had found specifically, and that was that genital use -- frequent genital use of talcum baby powder, talc without asbestiform fibers, increased the risk of cancer. And they talked about it as being a possible human carcinogen based on sufficient evidence in humans, and I believe insufficient evidence in animals. I may have that wrong but, yes, I think that's right.

- You mentioned it was a statement. Was it 0 something called a material safety data sheet?
 - Α Yes, that's correct. I didn't know if you

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wanted me to use the term yet, we hadn't introduced it, but yes.

Why don't you explain what a material safety 0 data sheet is, often referred to it as an MSDS sheet. Explain to us what that is.

Sure. It is common in my experience -- in fact, I've even written these before -- when you're an ingredient or chemical supplier that when you develop a product that you're going to sell, when you sell it, you ship it with a sheet of information that tells the customer everything you know about the product in terms of it could impact safety of either people that have to handle or information that could be relevant to passing onto people you may use that ingredient in making something else.

So it's the idea that maybe this is information that could go into labeling for products, for example. That will often be what some of that information is used for.

But it is a requirement, for example, to ship chemicals in interstate transport in the U.S. that you have to have some type of safety information for a company. So the MSDS sheet is a very typical one and the companies keep them on file typically also for their workers to protect their workers as well so they

Page 640 understand, if you want to understand, what it is that 1 2 you're being exposed to, you can go find out how that 3 could potentially affect your health. Did you review the material safety data sheet 4 0 that the talc supplier issued in this case? 5 6 Α Yes, I did. 7 MS. O'DELL: Your Honor, at this time, I'd like to move into evidence P2561, which is the 8 9 material safety data sheet. 10 Any objection? THE COURT: MS. BROWN: 11 Yes, Your Honor, I object. 12 Legal basis for the objection. THE COURT: 13 MS. BROWN: Hearsay. Overruled. It shall be received 14 THE COURT: 15 over objection. 16 Into evidence. THE CLERK: 17 (The referred-to document was marked into evidence as Plaintiff's Exhibit 2561.) 18 19 Thank you, Your Honor. MS. O'DELL: 20 Would you mind putting up P2561? Thank you. 21 BY MS. O'DELL: 2.2 0 Dr. Plunkett, is the material data safety 23 sheet you were describing? 24 Α Yes, that's correct. 2.5 Q Just to give us the reference again, this was

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issued initially by the talc supplier in what year?

A In -- well, this one may be 2009, but it was originally issued in 2006.

- Q Okay. And were they the same throughout the time period?
 - A Yes, they were.
- Q Have you reviewed them all throughout the relevant time period?

A I've looked for ones. I don't know if I've seen every year, but I certainly have seen them from 2006 and, like I said, I think this one may be 2009.

MS. O'DELL: Gina, if I may, may I ask you to turn to page 3 of the document? Thank you.

BY MS. O'DELL:

Q And could you direct us to the warning, the carcinogenic status that's contained in the MSDS sheet.

A So down here where you see IARC, under carcinogenic status, it lists IARC and it says 2006. That's the year they made the -- drew the conclusions, the panel met, and you'll note it says "in preparation," that's because the document wasn't published until 2010. And they stated that "IARC has concluded that perineal use" -- that's genital use -- "of talc-based baby powders is possibly carcinogenic to humans."

Then they also point out this is not a route

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of exposure relevant for workers and applies to one

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specific use of talc only. And since these documents

3 are often important for information for worker safety,

that is an appropriate statement that I'm not surprised

5 they put in there.

> And I don't know that we've used this term before, it says perineal use of talc-based body powder. What does that mean?

Α That means genital use. So the perineum is an area on the women's body that is in the area of the genitals, and it's the idea of application externally on that area. And that's what the conclusion was that was reached on the studies that had been done. studies had been done over the years that have reported an increased risk of cancer in women exposed by that route.

Now, were the material safety data sheets information that was received from the talc supplier by Johnson & Johnson?

Yes, that's correct, and there's testimony that I've seen that indicates that that was the case for In other words, I expected it and the testimony is that that had occurred.

So the talc supplier provided information that 0 perineal or genital use of talc based baby powder is

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possibly carcinogenic to humans. Was that information conveyed to consumers?

- No, it was not. А
- And so based on the standard, the warning 0 standard that we talked about previously, which the label of a cosmetic product shall be a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product. In your opinion, would this material safety data sheet, among other evidence, but would this particularly have triggered a duty on Johnson & Johnson's part to warn consumers?
 - Yes, I believe it did.
- Let me just ask you, Dr. Plunkett: I have a bottle of baby powder here. Sorry it's in a plastic bag because we don't want to let any of the compounds spill out in the courtroom, but is this a bottle of Johnson's baby powder?
 - That's correct. Α It is.
- And I'll hand it to you. And let me just ask Has Johnson's baby powder ever contained a warning regarding cancer risk?
 - А No, it has not.
 - Does that bottle contain a warning? 0
- Α No, it does not.

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Q And in looking at that bottle and, after your review of bottles -- let me ask you this question: Have you reviewed numerous bottles of different types of bottles that have been, you know, on the market of Johnson's baby powder over the years, it's changed shapes and, to a certain degree, the label, have you reviewed many of those?

A Yes, because there's discussion of that -actually, there's discussion of some of that in the
literature, but there's also example bottles that I have
seen. And then I've also, at one point in time, I
believe in 2017, went and did investigation on my own
just to see what was out there and if it was any
different than what I was aware existed.

Q From your review, from your information in this case, has the label for Johnson's baby powder ever listed asbestos or fibrous talc as ingredients?

A No, it's only ever listed the terms talc and fragrance.

Q Okay. And so, Dr. Plunkett, as a result of these constituents or these ingredients or components of Johnson's baby powder we've discussed, asbestos, fibrous talc, and platy talc, do you have an opinion as to whether the genital use of Johnson's baby powder creates a hazard?

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A Yes, I do.

- Q And what's your opinion?
- A It's my opinion that, indeed, there is a hazard to health, a potential for harm based on the presence of the asbestos and the fibrous talc, as well as the platy talc, within the Johnson & Johnson baby powder.
- Q And in light of these carcinogens that you've mentioned, do you have an opinion as to whether there should have been a warning on the label of Johnson's baby powder that genital use of baby powder can cause ovarian cancer?
 - A Yes, it's my opinion that it should.
- Q And as a result of Johnson & Johnson failing to list on the label all the constituents, not just platy talc and fragrance, but also asbestos and fibrous talc, do you have an opinion as to whether the product was misbranded?
 - A Yes, I do.
 - Q And what's your opinion?
- A That it was. That would be consistent with not having an accurate listing of what was actually in the bottle so a consumer can understand that.
- Q In light of the presence of asbestos and fibrous talc, under the regulatory framework, was

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Johnson's baby powder adulterated?

Yes, that's correct. Particularly on the issue of asbestos, which would be recognized as a contaminant.

- Was Johnson & Johnson's actions, failing to warn consumers of a cancer risk, inconsistent with actions of a responsible cosmetic company?
 - Α Yes, I believe it is, or was.
- Was it consistent with the duties or actions 0 of a responsible company?
- Oh, no, I'm sorry. I misunderstand your question. No, it was not consistent with what a responsible company should have been doing with the information, in my opinion, many decades ago.
- And you mentioned earlier that you had looked at the bottles or the packaging labels of other body powders. Based on your review, have other manufacturers warned of the risk of cancer as a result of the using body powder?
- Yes, in 2017, I identified some bottles that were made by others, other than Johnson & Johnson, that had a warning similar to what was found in the IARC statement about the relationship of genital use of talcum body powders and an increased risk of cancer.
 - Q So, Dr. Plunkett, let's transition a little

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bit from sort of focusing solely on the label and the regulatory aspects to the process by which talcum powder can cause ovarian cancer.

Have you prepared a slide that helps describe, in very general detail, a general way the mechanism by which baby powder can cause ovarian cancer?

A Yes, I have.

Q Okay. All right. Dr. Plunkett, why don't you walk us through what's being depicted on this slide.

A So I'm showing here that there's four basic issues that I think are important to consider when you're talking about how Johnson & Johnson's baby powder causes ovarian cancer. The first issue has the bottle shown here.

The second is the first step. You have to have exposure. So it's the idea of what does the scientific literature show and what do we know, and indeed -- and I think we are going to discuss this a little further, but there is evidence to show that, indeed, particles of talc can travel from the outside of a women's body into the vagina, up the reproductive tract, and can end up in the area of -- through the fallopian tubes in the area of the ovary as well as in the peritoneal cavity of the woman.

So it can travel from the outside to the

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inside. With that exposure, there's scientific literature, both at the level of cells and tissues, as well as in animals or whole animals, and also, we also have studies I've relied upon that talk about the relationship of inflammation to cancer, how cancer forms in humans. And so inflammation is the process that is produced by the presence of the talc particles within the tissue of the woman's body.

And then the inflammatory process is the mechanism that has been linked to ovarian cancer in a large proportion of the ovarian cancers that are seen in women, particularly the types of cancers that are at issue in these cases.

Q Okay. Would it be helpful to describe sort of the female anatomy and sort of how talcum powder can enter from the perineum enter the female genital tract?

A I think so. And not everybody may be familiar with it themselves.

- Q Have you brought an illustration that might be helpful in that regard?
 - A Yes, I did.
- Q And I'm going to hand you the clicker. If you want, you can -- so tell us -- would you walk us through and just describe for us the anatomy and how it's relevant to how talc can migrate.

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So first, this is a picture as if I was standing here and you were cutting me down the middle of the body. So you are looking down through the middle, and what's shown here are some of the structures we are going to talk about, I think with some of the studies in data or science. So you have the label here for the vaqina.

MS. O'DELL: Your Honor, would it be okay if Dr. Plunkett approached the screen?

> THE COURT: She can.

MS. O'DELL: May I hand her a pointer?

THE COURT: Yes.

MS. O'DELL: Thank you.

THE WITNESS: So the vagina -- so this is the outside of the body. We have the labia, which are the tissues that are outside the body that are around the outside entrance to where the vagina enters the body. So we have the vagina here, we are going up. This is a cross-section cutting through the uterus.

You enter here to the interior the uterus, so vagina to uterus. Just down here is the bladder, just to orient someone if you're interested in that.

Then you'll notice that the uterus and then up

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here, you have the fallopian tube, this is the ovarian sac. You can see it showing some eggs in the ovarian sac. This is all suspended within the peritoneal cavity, so in the abdomen of the woman.

So what we are going to talk about with migration is the evidence and the science that shows that you can move upwards in the reproductive tract, and that is something that's understood that this happens in women. Things don't just fall out. Things can actually move up the tract as well.

And we are going to talk about the migration from the talc outside the body where it's sprinkled on the perineal area, genital area, maybe in your underwear, and then the passage through the vagina, into the uterus, and then up into the upper regions of the female reproductive tract. There was another slide that shows it frontal on, which is probably a little easier to see, particularly how the uterus and the fallopian tubes are connected.

So again, we are coming through the vagina, through the cervix, into the uterus, into the fallopian tubes, into the area of the ovary, and again, these are suspended within the abdominal cavity or the peritoneal cavity.

MS. O'DELL: Thank you very much.

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BY MS. O'DELL:

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Q Dr. Plunkett, have you reviewed literature that describes the ability of particles applied to the outside of a woman's genital area to be able to ascend the genital tract to the ovaries?

A Yes, I have.

Q Okay. And what was the first study that essentially put the scientific world on notice that this process could occur?

A The first one I could identify in the scientific or medical literature was from 1961. The first author was named Egli, E-G-L-I, and he was a doctor and provided data on women where he -- they were getting ready to have surgery and he showed that the placement of carbon particles into the vagina, that those particles were moving up very rapidly and quickly and going through the women's reproductive system and ending up in the peritoneal cavity. The idea that things were moving through the reproductive tract and not just sitting where they were deposited in the vagina.

Q And have you seen evidence that Johnson & Johnson was tracking the literature and was aware of this study when it came out in the early '60s?

A Yes, I have.

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Have you also reviewed a number of other papers that have described sort of the mechanisms by which talc can migrate to the ovaries?

Yes, I have. Α

And is this slide a summary of at least some 0 of the articles that you have reviewed and the data that's helped inform your opinion?

Α I mean, there's more than a dozen, maybe close to 20 different articles that I have reviewed and relied upon, and these are just four that were earlier in time, in the '60s and in the '70s, that I thought provided sort of an overview of what you can find in the literature.

Okay. And we've talked about the Eqli study, the first study in 1961. You've also included, on a slide, a reference to the Henderson paper in 1971.

What was the importance of the Henderson paper and what it said to address this question?

Α So it was the first paper I found that actually was describing the presence of talc in variance tumor tissue in samples from women who has ovarian tumors and it is one, again, that -- well, it's the first one that I saw that described it that way and it also was another of those studies that evidence in this case shows that the company was aware of as well.

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And are all the studies that you have on the 0 screen peer reviewed?

Yes, all of these come from what is referred Α to as the peer-reviewed public literature, and all of these are in the medical literature.

And so the Henderson paper was published in 1971, and you mentioned talc was found in the tissue. think it said it was deeply embedded in the tissue; is that accurate?

Α Yes. And that's important because the issue would be is it something that was a contamination due to the way that the tissue may have been looked at in the lab or was it actually something that was there before the tumor or at the early stages of tumor formation or before the tumor formed. And that's what the paper is talking about.

It's talking about the importance of finding it deeply embedded in the ovarian tumors. And the authors even discuss that as related to the etiology of the cancer in the paper or why the cancer formed -- I shouldn't use that word, etiology -- why the cancer formed in those particular women.

And you've also included a study that's 0 referred to here as Parmley and Woodruff in 1974. Would you tell us about that study and why you felt it was

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relevant to your analysis in this case?

A So I put this one on the slide because it was probably the earliest study that I saw on paper in the literature that I saw that was actually generalizing and discussing the fact that, in the author's opinion, that substances can gain access from the outside to the inside. They have a crude drawing that they put in the paper showing particles moving from outside the woman's body up into the peritoneal cavity. And they talk about how a woman's body is different than a man.

A man's body, that isn't a route that can occur. But environmental substances, they even talk about it in terms of substances in a woman's environment, have the ability to move from outside the body to inside and how that could have implications for women's health.

Q Thank you. And you included one last study, also an early study, the Ventner study. Tell us about that just quite briefly and why it informed your opinion.

A So this was a little bit later study than the Egli study, but it was another study that was done in women that were getting ready to have surgery. They put, into the women's vagina, particles that were of a size that would be similar to the types of particles,

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very small that you might have of a substance coming from the environment, like a platy talc coming in into the women's vagina.

They put it in there and they showed that and they talked about the fact that, in this particular study, the particles were able to, again, easily move upward into the women's reproductive tract from where they were deposited into the uterus, the tubes.

They talked about the connection of the outside to the inside of the women's body. So in the '70s, you see papers, and then later in the '80s and '90s as well, where the physicians and the investigators are talking about this -- the importance of understanding this as a potential route of exposure to women in terms of environmental substances, things coming from outside, particularly with particles and talc is a particle.

Q Did these early studies -- did they put
Johnson & Johnson on notice that a woman who was using
the talcum powder on her genital area could be exposing
her reproductive tract, her fallopian tubes, ovaries,
and the peritoneal cavity to talcum powder and its
constituents?

- A Yes, in my opinion, it does.
- Q I want to ask you about just the functioning

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of the vagina and how physiologically the way the female reproductive tract works could assist in particles moving upward.

A Okay.

Q Would you describe that and tell us what it is and how it informed your opinion?

A So I think maybe a little bit after this '70s timeframe, there were publications in the literature where physicians are describing something called the peristaltic pump, and it was talking about the fact that, in certain times during a woman's ovulatory cycle, that the contractions of the vagina, as well as the uterus, are assisting things moving up instead of out. And it's the idea that those contractions of the vaginal wall, as well as the uterus, are providing a mechanism whereby things are able to be transported more rapidly.

It was first being discussed because it was trying to understand, with sperm, how quickly can they move from the time they are deposited in the vagina until they get up to the ovary, and they were interested in looking at that issue and understanding physiologically what was going on. After this time period, I think in the '80s and '90s, it was being discussed as an understood phenomenon for explaining the fact that is correct women's reproductive system is not

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a one-way tract out with menstrual flow, but it's actually that things can go up as well as come out.

There's papers also, I think a 2004 paper that I cite and I talk about in my expert report that talks about the fact there may be a misconception that, indeed, the way the woman's anatomy is that it's a gravity-driven, directly down route of entry, but it's The first slide I showed a little bit on the not. women's anatomy cut this way, there is an angle to it.

So it's not that it's just gravity-driven directly out, but indeed there is an angle once it's in. And if you have these contractions, there is an understandable way where -- why it is that you would not expect things to just fall out of the women's reproductive system, which is, I think, something people may think, that things would just fall out. That is not what's going on here.

And so those papers were all really informative to me in forming my opinions about migration and are consistent with what I see discussed in the medical literature, even up to today, and FDA has even commented on this as well.

And what was FDA's comment on whether 0 particles would migrate to the ovaries and fallopian tube?

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So in 2014, there is a document that FDA put out that talks and uses the word indisputable. It says that particles can migrate from the outside to the inside and that evidence is indisputable.

MS. O'DELL: Your Honor, I've moving to another topic, which I'm happy to do. I didn't know if the Court was --

THE COURT: You're good.

BY MS. O'DELL:

Let's transition. You talked about the overview, migration, then you moved to inflammation, so let's talk about inflammation as you've described it. Doctor, so what is the process by which talcum powder and its constituents -- asbestos, fibrous talc, platy talc, et cetera -- can cause cancer?

So there is a large -- by this time, today, there is a large body of scientific evidence to show that these constituents, the asbestos, the fibers of talc, the platy talc all have the ability to induce a physiologic process called inflammation. So it's an irritation essentially, that's a broader word that you can use.

But it's actually a very specific physiological process where there's an injury to the tissue by the presence of the particles in the area of

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the tissue, and that, by continued exposure to particles, there is an initiation of a process that then leads to changes in the cells that are being injured, such that, instead of being normal cells, they become abnormal cells.

And there's scientific evidence and information that shows that that process, in some cases, can lead to a triggering of a change in the cell, such that it's not just abnormal but it becomes a cancer cell. So it's a process that underlies that.

And again, it's a generally well-accepted link between cancer and what we call chronic inflammation or unresolved inflammation inside the body. You can't see it with your eye.

You and I can see inflammation on our skin if we cut ourselves. It gets red, we may get swelling it, it may itch. That's an inflammatory process that is a healing process.

But inside the tissue, what's happening is that inflammation is not shutting down, it's continuing, it's unresolved, and it leads to a series of changes that take normal cells and make them abnormal cells and eventually cancer cells.

0 And Dr. Plunkett, I want to ask you, you used some terms in your answer sort of and you talked about

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inflammation. You mentioned acute and chronic. to step back a minute.

And have you prepared a slide that would help discuss that? I know you've mentioned some things, but could you talk just a little bit more about the differences in those types of inflammation?

So this is just -- I prepared this just to kind of make sure everybody understands that inflammation can resolve, and it can be the kind of inflammation you see if you cut your finger, have trauma, maybe you burn yourself. Most of the time, that will heal.

So that is an inflammatory process, and some of the same changes or chemicals within the cells, in cells that are injured, are leading to a healing process. But what happens with chronic inflammation, inflammation that doesn't resolve, that's what the kind of inflammation we're talking about it, and it actually progressively destroys tissue and actually leads to cancer.

So it is -- inflammation is not all bad. Initially, inflammation can be good because it can help you lead to the healing, but if it goes unchecked, it leads to tissue destruction, changes in cells such that you can actually get a cancer cell formed.

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Q And Dr. Plunkett, have you prepared a slide that will help us understand how chronic inflammation can lead to these changes that lead to cancer or tumors?

A Yes. It's a stair step slide.

Q I want to ask you, please, if you would just walk us through it step by step, you know, from the exposure, in other words, talc gets in the genital tract to the fallopian tubes and ovaries, and then how that can lead to ovarian cancer.

A So first off, each of these little boxes are stair steps here. I've prepared and I put some wording in here, and the wording is there because I have scientific studies or literature that describes these things. These are actually pieces of evidence that you can find within the medical literature.

So we talked about talc particles being able to get inside the body into the fallopian tubes and the ovaries. That's the first step.

Once it's there, what is occurring is the science would show that you can get a local injury within the tissue area and you will initiate inflammatory process. So that initiation of inflammation in the next step, if it does not resolve, is going to actually lead to damage to cells.

Some of the damage that can be caused by that

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inflammatory chronic process is actually something called mutation. People have heard of mutations in cells and people think of mutations as being linked to cancer. Well, that is true.

You can also get though, in addition to the damage to cells being a mutation, the other thing that can happen is you can change the cells so that it is no longer producing the same kinds of things it did before and it actually makes the cell take on new characteristics, and that's number four. The cell now becomes an abnormal or what's called a precancerous cell. Genes are turned on.

Genes of the parts of the DNA that control the machinery of the cell, what the cell does, and with the presence of that chronic inflammatory process, that machinery of the cell changes and the cell becomes abnormal. After the cell becomes abnormal with those changes, it can actually take on the characteristics of a cancer cell, that's step five.

Cancer cells have the ability to divide. They have the ability to be something calls immortal. means they don't die. They tend to just keep dividing rapidly and continue to grow. The cells continue to accumulate and you get a tumor eventually, and that's the next step.

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You get the cancer cells that accumulate, you get the tumor due to the cell division, the proliferation of the cells at the site at which the injury and inflammation was taking place. And so the cancer cell has that ability to divide. It has the ability also to produce certain new chemical mediators within it that promote the cancer in terms of it continuing to develop.

The other thing that could happen is you could -- the cells can change such that you can stimulate the formation of blood vessels, and you need that because you need the blood to be brought in to bring nutrients to the cell so it continues on that rapid growth phase.

So again, this was -- all of these steps here are ones that are either well understood in carcinogenesis, inflammation is a well-known mechanism underlying carcinogenesis, including ovarian cancer, and we have data to show that talc can do some of these things to initiate inflammation. We can show that asbestos can do that.

We can show, from the literature, that fibers, such as fibrous talc, can do that. And all of those things are along the way to leading a cell from exposure all the way to the tumor. So this is a mechanism that

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tells you something about why it makes sense that talc can cause cancer.

Q This is a part of your sort of explanation,
Dr. Plunkett. You mentioned mutations, you talked about
mutations.

Can mutations be inherited and some be acquired? And would you explain to us the difference, please?

A Right. So an acquired mutation in a cell means that it is something that's handed down through mother to daughter, mother to son, it comes from the DNA that you have when you're born. So that acquired mutation is there and it --

- Q Did you say acquired or inherited?
- A Inherited mutation.
- Q I think you misspoke. Would you mind saying that again?

A So an inherited mutation is one that comes through your DNA from the time that you're born. An inherited mutation is one that can sit there and not cause a problem, but some time in your life can actually result in some physiological change and it can manifest as a cancer. Sometimes those inherited mutations, however, can remain dormant. It just depends.

An acquired mutation is what's occurring in

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this type of situation where a chemical or an exposure is damaging the cell, damaging the DNA, causing a mutational event such that the mutation then causes the cell to change in some way. So acquired mutations is what we're talking about here in this process with the chemical exposure, even though it's true that there are, for example -- maybe the one that most people know about is breast cancer -- there is a gene that you can inherit from your mother, it's called the BRCA gene, and that's an example of an inherited mutation in your DNA that puts you at increased risk for breast cancer, for example.

Q And does it mean you are going to get breast cancer?

A No, not everybody who carries the gene gets breast cancer. There's a whole discussion there, but I think you have other experts who are going to handle that.

Q I do. So let me just ask you, Doctor: As part of your explanation also, you're talking about the evidence that you've seen that talc itself can induce an inflammatory response or inflammation at the cellular level.

And have you reviewed studies that have been published in the literature that show that?

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Yes, that's one of the things that I was looking for when I was doing my literature search. was looking for the evidence that showed, not only did we have human data or animal data, but what was actually going on at the level of a cell.

- Have you prepared a slide that sort of summarizes some of those studies?
 - Α Yes, I have.
- 0 And so let me just ask: Why, when a cell study is done, let me start there, what happens? you say cell study, I know before you explained this to me, I had no idea.

So what is a cell study and why are those important?

So a cell study means that you have isolated particular types of cells. In the case of this table, I have some cells that have been isolated from humans and some cells that have been isolated from animals, in this case, a mouse.

And the reasons these kinds of studies are done is it would be unethical to expose a person and then take their cells for purposes of understanding a mechanism like this. Instead, what you do is, if you want to understand a mechanism, you will take cells first and look at whether or not the chemical or the

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exposure that you're worried about has the ability to induce changes that you think could be linked to the toxicity or the injury you've seen in humans. And so that's what these cell studies are.

They are studies that were done in order to understand how it is that talc can injure a human being and you start at the level of the cell because that's the underlying mechanism for cancer that we are investigating.

Okay. And what have the cell studies that you have reviewed, general, what have they demonstrated? What have they shown and why is it important?

А So the cell studies have shown that changes -they've shown that cells have been injured, harmed, or adversely affected by the exposure to talc, be it platy talc, fibers, or asbestos. All three of those things have the ability to make changes in cells that are consistent with either inflammatory mechanisms or some other type of change that's related to cancer formation. It isn't that you are measuring cancer in the cell, you are measuring early changes that we now know are consistent with the changes that have been shown to be linked to cancer.

So it's like we are going down, we are taking -- we are going from here is the tumor and cancer

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we see in a human and we're trying to go backwards and understand how it is that could have happened. So we start by looking at what happens if you expose, for example, a human ovary cell, that's the Buz'Zard study. Take ovary cells from humans, expose them to talc, what happens?

In the Shukla study, we did the same thing.

We took ovarian cells, put them in a petri dish and they grow them and they expose them to talc, also they did asbestos in that study, and they looked at what happened and you can measure different things.

You can measure genes that change, whether or not the cells take on characteristics by producing chemicals that can lead to inflammation. You can look at whether the cells take on the ability to proliferate, to divide rapidly in the presence of the chemical. So those are things that are discussed in this table. They are end points, the findings column or the end points that were measured.

Q What do you mean by "end point"?

A They are the biological events that they monitored, the things they looked for in the cell. So each study could only look at so many things, and so the Buz'Zard study, for example, focused on cell proliferation, it focused on the production of

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inflammatory chemicals in cell, inflammatory compounds. It also looked at whether or not the cell took on characteristics that were indicative of a cancer cell.

Whereas, the Shukla study was focusing on gene changes. It looked at whether or not certain genes that were in the cell, in the DNA of the cells, were changed in a way that they became pro-inflammatory such that they were producing -- had the ability to lead to the production of chemicals that were associated with an inflammatory process.

So it's a lot of weeds here in these studies, but as a scientist, this is where you would start when you're trying to understand, again, why it is that it makes sense that talc could cause cancer. You would want to see changes with these types of cellular studies that then you could investigate in a whole animal to actually look at tumor formation or look in human studies to see whether or not you were seeing a relation between exposure to talc and increased numbers -- increased women with ovarian cancer, for example.

Q In addition to these four studies you summarized here, Doctor, have you looked at other studies that have examined the impact of talc at the cellular level?

A Yes, there's dozens of studies out there that

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you can look at. Depending on the way the study was designed, you are going to look at different biological changes.

The other thing you can do in a cell that's harder to do in a human is you can control the exposure So what I mean by that is you can take talc and you can put it in a low level or you can put it in at a high level, and same thing with asbestos, you can put in a low level or high level, and you can see whether or not the level of exposure is affecting. It's called the dose, whether that affects the response you get.

So those are all things you can do in a cell that you couldn't do ethically in a whole human study, for example.

Have the results of the cell studies you've looked at all been consistent that talc can induce inflammatory changes?

Α Yes, that's the consistency across all the They all are linked -- almost every study that you see has something in it that relates to a change that would be indicative of what I call pro-inflammatory state, inflammation being either started or inflammation continuing because of the presence of the talc.

0 This morning, in opening statements, counsel for Johnson & Johnson mentioned something called

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neoplastic transformation. And one, I'd like you to define that for us, and then I have a question for you.

Okay. So the simple definition for me is Α actually in my first box. I say here, this talc at the end caused ovarian cells to take on characteristics of cancer cells.

Neoplastic transformation is a term that is used in the cell studies to mean that whatever it is you're looking at, that cell is taking on the characteristic of a cancer cell. It's not that it is a cancer cell, it means that it is taking on the characteristics for that.

And there's different ways that scientists look at that, different end points, different ways to do it, but that's a term -- I'm not sure what was being referred to, obviously I wasn't here, but I've seen that in the literature people have talked about. And this paper by Buz'Zard reports on this issue of neoplastic transformation in the cells. And when you read it, it's talking about the cells taking on the characteristics of a cancer cell.

And in that paper, the Buz'Zard paper, was it 0 talc-like substance that caused neoplastic transformation?

Α Yes, that's correct.

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Q And in order to -- are cell studies still relevant, whether they document neoplastic transformation or not?

A Yes. They are absolutely relevant because the issue is, in these cell studies, understanding what is the initiating event. And if the initiating event we are worried about is chronic inflammation, the fact that you're not measuring neoplastic transformation is not the issue. The issue is: Are you measuring something in these cell studies that can then be tied in with the biology of an animal, for example? And that would be a chronic inflammatory process.

There is an animal study, I think we are going to talk about later, that the important part of that study it has to do with looking at the tissue level and whether you're seeing inflammatory changes with exposure to talc.

Q Okay. So in conclusion, in regard to -- let's back to migration just for a moment.

Doctor, do you have an opinion as to whether talc applied to the genital area can migrate to the fallopian tubes, ovary, and peritoneal cavity?

- A T do.
- Q And what's your opinion?
- A The evidence in my view shows that it can

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Page 673 1 migrate from the outside to the inside and up the 2 reproductive tract. 3 And once there, do you have an opinion as to 0 4 whether talcum powder can cause chronic inflammation? 5 Α Yes. And what's your opinion? 6 0 7 Again, the evidence is clear, in my view, showing that the weight of the evidence shows that 8 9 inflammation can be caused by exposure to talc in 10 tissues and cells, including those into the reproductive 11 tract. 12 Have you prepared an animation that depicts 0 13 the process of migration and inflammation? 14 Yes, I tried to depict that, yes. Α 15 0 Did you direct its creation? 16 Yes, I did. А 17 And, in fact, do you narrate it? Q 18 I do narrate it. Α Based on your review of the scientific 19 0 literature and your expertise and your training, does it 2.0 21 accurately and fairly depict the process? 2.2 Α Yes, the overall process. And it's kind of that four step process we had earlier from the bottle to 23 24 inside the woman and into the inflammatory process. 25 MS. O'DELL: Your Honor, at this time, I'd

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like to play it.

THE COURT: Well, we're going to take a break. About ten minutes. We're going to let you go out here and stretch. Leave your notepads on your chair, turned face down. Remember you cannot discuss the case among yourselves or with anyone else.

(The jurors exited the courtroom.)

THE COURT: Can I ask the question: Is this animation that you're referring to, is it actually going to be what she just testified to?

MS. O'DELL: In many respects, yes, sir.

THE COURT: Why didn't you play the animation when she was testifying to it?

MS. O'DELL: Because I wanted to make sure I laid an adequate foundation so my counsel on the other side would not object to it.

I don't understand. She says that THE COURT: the animation is basically the four steps that she just testified to. So if that is the animation, the only foundation you would have to lay at that point was: Did you create it?

MS. O'DELL: Fair, Your Honor. But if you see it without having laid the foundation, it's really hard to understand what's being depicted.

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THE COURT: No, no, as she's testifying, she can say this is step one, this is it as it's migrating into the vagina, then it then moves here. This is step two, what is step two, she says what it is, and then it migrates to here. She is just going to say that is all again.

MS. O'DELL: It's a very short, 20-second animation. It just shows it and I think it just cements --

THE COURT: Okay. There was no objection.

MS. O'DELL: Thank you.

MS. BROWN: Your Honor, it wasn't played yet and I would object as cumulative given that she just described it in very great detail.

THE COURT: Okay. You have to use the bathroom on a lower floor, unfortunately. You can use the one in the jury room after, of course, our court reporter uses it. We'll be in recess.

(A recess was taken at 3:14 p.m. and the proceedings resumed at 3:23 p.m.:)

THE COURT: The jurors asked whether or not -- and I've got to tell them to stop asking the bailiff questions, but they asked whether or not they can bring their own lunch and, of course, they can and I'll tell them they can.

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Page 676 1 MS. BROWN: Your Honor, we do have that snack box whenever you want us to give it to the bailiff. 2 We had talked about putting the snack box --3 THE COURT: You have what? 4 5 MS. BROWN: Snack box for the jurors in the 6 jury room. 7 THE COURT: Can we just put it in the jury 8 room now? 9 MS. BROWN: I think it's upstairs. 10 THE COURT: No, we can do it tomorrow. This 11 is the last break for the day before we end the 12 day. 13 MS. BROWN: Will we go to 5:00, Your Honor? 14 THE COURT: Probably 4:30 p.m. 15 Jurors coming in. 16 (The jury enters the courtroom.) 17 THE COURT: All right. For the record, all 18 the jurors are present making their way to the 19 seats. All the parties are present. The witness is on the witness stand, still under oath. 2.0 21 Everyone can be seated, get comfortable, please. 2.2 A couple things. One is that, yes, you can 23 absolutely bring your lunch. You do not have to 24 buy lunch every day. You can bring your lunch. 25 Two, you have to make sure your phones are

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away, okay? You cannot have your phones out during the testimony.

If you need to take a break, if you happen to get an alert and happen to look at it and you need a moment, just say, Judge, can I take a moment, I got to get this, and we'll just say no problem, go into the jury room and do what you need to do, okay? But you can't be on your phone while the testimony is ongoing. You may continue your examination.

MS. O'DELL: Thank you, Your Honor.

BY MS. O'DELL:

0 So, Dr. Plunkett, we talked a lot about inflammation. I want to ask you sort of a question about what Johnson & Johnson knew about inflammation.

Have you seen evidence that would establish that Johnson & Johnson has known that talc causes inflammation for at least 75 years?

- Yes, I have. Α
- What is that evidence? 0

So there is a publication from 1947, I believe, or '48, that is published by at least two authors that were employees at J&J where they were looking at the effects of talcum powder versus an alternative type of powder for use on surgical gloves,

Page 678 1 and the paper describes the issues that were known at the time in terms of the toxicity of talc to tissues 3 when it was deposited internally, for example, on a 4 surgical glove. 5 MS. O'DELL: And for demonstrative purposes, Your Honor, I would like to display P5003, which is 6 7 the study that Dr. Plunkett has just referred to. THE COURT: Okay. 8 BY MS. O'DELL: 9 10 Just very quickly, Dr. Plunkett, I would like 11 for you first to focus on the authors. Who were the 12 authors? 13 Δ So the authors are listed. You'll see Eberl, 14 George, May, Henderson. Those are the last names of the 15 individuals. The first one, James Eberl is relevant to 16 another document that we may or may not discuss where he 17 was actually an inventor on a patent related to this new 18 type of powder to be used on surgical gloves. 19 Q Okay. MS. O'DELL: And in regard to talc, I would 2.0 21 ask you, Gina, to go to the second paragraph, 22 please, in the middle. 2.3 BY MS. O'DELL: 24 What did it say in terms of evidence of talc 0

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being an irritant?

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In the paragraph I read above this, and then up to this sentence is discussing the fact that studies have shown the talc can be an irritant, and they say here that these studies offer incontrovertible evidence of the local irritant action of talcum.

And what was being proposed as a result of that understanding that talc can cause an inflammatory response?

Α So the idea was because of the harm or danger posed by the presence of talc when it's deposited internally into tissues, they were looking for a new alternative substance that could be used to dust the gloves. So what the talcum powder was there for was in order to make the gloves easier to go on and off by the surgeon, and also, to absorb some sweat, heat that gets under the gloves.

And the idea was they were looking for a satisfactory substitute. And this paper is describing studies they were doing looking at substitute substance.

- And are at least two of these authors, were 0 they employees of Johnson & Johnson?
 - Α Yes, that's correct.
- Do you see that at the bottom of page 1, at 0 the bottom, it says from the laboratories of Johnson & Johnson?

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Yes, that's correct. And again, you can confirm these two names when you look at the patent applications too.

You mentioned a patent application. Let me just ask you: So this study that we were talking about, the Eberl study, was in 1948. So employees of Johnson & Johnson were on that study documenting that talc was an irritant, there needed to be a substitute. And what were the next steps? What did they do following that study?

So they did what people that I work with, that inventors do, they take that information and they seek protection in the patent world so that they can commercialize those products with that particular invention or new thing they have found that could work. So they sought a patent in 1953, maybe, I may be wrong on the dates, five years later, four years later.

Let me stop you right there. Did Johnson & Q Johnson obtain a patent on cornstarch as a substitute for talc?

Yes, and I guess we didn't say that the new powder they had developed was a cornstarch derivative. So they were using cornstarch as the base to make this new powder that they were using.

Q And did you review that patent?

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Page 681 I did review that patent. Again, it's something that I do all the time, so it was very interesting for me to look at that. And you did that as part of your work in this Q case to reach your opinions? Α I did, that's correct. MS. O'DELL: And, Your Honor, at this time, I'd like to move into evidence Plaintiff's Exhibit 2559, which is the patent application. THE COURT: Any objection? MS. BROWN: No objection, Your Honor. THE CLERK: Admitted into evidence. (The referred-to document was marked into evidence as Plaintiff's Exhibit 2559.) MS. O'DELL: I'll direct you to page 2 of the patent. BY MS. O'DELL: Dr. Plunkett, when was the patent issued? Q In 1953. January 20, 1953, that was on the Α first page. And who were the owners of the patent and who are they?

Α Okay. So the owners of the patent are actually the employees. And it says here -- when it says assignor down here to Johnson & Johnson, a

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corporation of New Jersey, and the other owner was the National Starch Products, corporation of Delaware.

So when you're an employee and you develop a new product, typically your employment relationship means that if you invent something while you are an employee, you have to sign the rights to your patent to the company you work for. So that means the patent now becomes owned by the companies that the people worked for.

So in this case, Mr. Eberl and I think -- maybe Dr. Eberl and Dr. George are the two listed on here that were employees of Johnson & Johnson.

Q And what was the invention that they were putting forward and what was the problem that they were trying to address?

A So the problem they are trying to address is found right up front in the patent where essentially they lay out, in this first section of the patent, what this invention can do that other things couldn't do and why it's important. And they talk about the toxicity of talc to tissues, the problem with talc as a medical dusting powder when it got internal and the fact that this new powder that they have developed overcomes the problems that we're seeing in terms of tissue toxicity.

And the other thing they point to is the fact

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that cornstarch can actually be absorbed in the tissue.

One of the things that happens with talc, the reason the irritation of the tissue is important is because the talc doesn't get absorbed. It just stays there.

It potentially can move away, it goes up the reproductive tract in women or it could move away a bit from the site of where it was deposited, but the point is, it doesn't get absorbed. Whereas, the cornstarch gets absorbed out of the tissue and becomes something that is no longer harmful in terms of irritation once it's absorbed.

Q Okay. And specifically, did they talk about just exposure to the vagina? In the patent itself, does it talk about exposure and is that in the second paragraph on the left side?

A Yes.

Q And Dr. Plunkett, explain to us what's being said in the paragraph that Gina has pulled up --

MS. O'DELL: Which is second paragraph, Gina, if you don't mind. So the second highlighted paragraph. Thank you.

THE WITNESS: So down here, it starts with
the -- the sentence starts with, "There were
literature reports." So they are referring to the
fact that it had been reported in the medical

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literature, and I have found that literature as well that talks about when talc was put into -- inside the body, that depending on where it was deposited, you could have injury or toxicity seen in the tissue. So what they were seeing what they called granuloma of the rectum, the vagina, the cervix, and the brain and various wounds, and they talk about it being caused by a contaminant like a podium or by talc that was traced to the surgeon's gloves. So essentially, surgeons did operations, some talc gets left behind.

There's other studies in the literature, by
the way, that talk about this particular event and
how very little amounts can be a problem. But
essentially, what they were trying to do here was
say here is our problem, we have talc, it can't be
left behind, it causes tissue injury, and now we
have developed a product that is different and
better, and that is what they lay out.

They show the data -- the Eberl study had data in it showing that cornstarch could be absorbed and that tissue irritation or injury was different with cornstarch as compared to talc.

BY MS. O'DELL:

Q You said the product was better.

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Page 685 1 MS. O'DELL: If you go down, Gina, to a little bit lower. So starting, "More particularly." 2 3 BY MS. O'DELL: Q Do you see that? Is this where they outlined 4 5 why the product was better? Yes. And so the language you see here, when 6 Α 7 they say more particularly the object, that's patent 8 language that lawyers use, people like me use. It just 9 means the thing we are inventing is something which is a 10 dusting agent that the two properties that this agent will have is that it is absorbable and it's harmless to 11 12 body tissues. 13 So they were trying to solve the problem with 14 the talc, which was the other way, injured body tissues 15 and was not absorbable. And that's what the object of 16 this invention is or the purpose of this patent is. 17 So does this patent make clear that since 18 1953, Johnson & Johnson has had a safer alternative to talc in powder? 19 2.0 Α Yes, that's correct. 21 And is that reflected in their own documents, 2.2 that they were aware they had safer alternatives to 2.3 talc? There is a number of documents that I 24 Α Yes.

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have reviewed and relied upon that talk about, over

Page 686 time, and after this patent, over time in the next 1 2 couple of decades where they are recognizing the fact that cornstarch could be absorbed safely in the body, 3 that there was a difference in the tissue injury that 4 was produced by cornstarch versus talc. And yes, it's 5 6 definitely something that was recognized from this time 7 going forward in discussions within the company. Is Plaintiff's Exhibit 2026 one of those 8 0 9 documents, J&J documents, that you reviewed and relied 10 on in reaching your opinions? 11 Α Yes. 12 MS. O'DELL: Your Honor, at this time, I move 13 into evidence Plaintiff's Exhibit 2026. 14 Any objection? THE COURT: 15 MS. BROWN: I just need a moment, Your Honor, 16 I apologize. No objection. 17 It shall be received without THE COURT: 18 objection. 19 THE CLERK: Admitted into evidence. 20 (The referred-to document was marked into 21 evidence as Plaintiff's Exhibit 2026.) 2.2 MS. O'DELL: Gina, I would ask you to blow up 23 the top half. BY MS. O'DELL: 24 Dr. Plunkett, is this a Johnson & Johnson 25 0

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Page 687 1 document? Yes, it is. Α 3 And what's the date? 0 4 February 21, 1964. Α 5 And what's the purpose as stated in the 0 subject? 6 7 Α The subject is they are discussing the 8 development of cornstarch as a powder. 9 0 Is this a report of a meeting that took place within Johnson & Johnson in 1964? 10 11 А That's correct. 12 And it says "present." Do you see that at the 13 top of the document? 14 Α I do. 15 Based on your review of depositions and 0 16 documents, what's your understanding of who those 17 individuals are at Johnson & Johnson? 18 Α So I don't remember their specific titles, but certainly all four of those individuals listed -- Faust, 19 Sundberg, Schoel, and Ashton -- are all employees that 2.0 21 were involved with baby powder and also sort of the 2.2 science issues or the -- some of the safety issues 2.3 around the use of baby powder. In this particular 24 document, they had been agreeing to or they were going 25 to be doing a consumer research test to test consumers

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acceptability of cornstarch.

- Q Okay. And if you'll turn to the third page in the document, what did they conclude about talc as compared to cornstarch?
- A So in the last -- you have it highlighted.

 They are talking now here about what went on. They say, since the meeting earlier up there the top of the paragraph, they are talking internally about the comparison of talc versus cornstarch. They say, as a condom lubricant where cornstarch replaced talc because it was found to be absorbed safely in the vagina where, of course, talc was not.

So it's pointing back to this issue of the fact that cornstarch in the vagina can be safely absorbed, whereas, talc is not.

- Q Did Johnson & Johnson ever tell the public that talc cannot be safely absorbed in the vagina?
 - A I've seen no evidence of that, no.
- Q Did Johnson & Johnson continue to consider cornstarch as a safer alternative to talc on into -- we talked about the '50s, '60s, into the 1970s?
 - A Yes, they did.
- Q And have you seen a memo where they are discussing talc as a safer alternative?
 - A Yes, I have.

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Page 689 1 MS. O'DELL: And, Your Honor, at this time, I would move into evidence Plaintiff's Exhibit 2041. 3 Any objection? THE COURT: 4 MS. BROWN: 2041? 5 MS. O'DELL: Yes. MS. BROWN: Your Honor, I have no objection to 6 7 the admission of the document, but I do have objections on the continued use of these documents 8 9 for the other reasons we argued. 10 THE COURT: Understood. It shall be admitted 11 without objection. 12 THE CLERK: Admitted into evidence. 13 (The referred-to document was marked into 14 evidence as Plaintiff's Exhibit 2041.) BY MS. O'DELL: 15 16 Is this a J&J document? 0 17 Α It is, as you see at the top. 18 What is the date? Q 19 April 26, 1973. So about nine years after the Α document we just looked at. 2.0 21 Okay. And what is -- just generally, we'll go 22 through it step by step, but what is this document reporting on? 23 24 So the subject of the memo or the document is Α 25 listed as Windsor Mineral, so they had a mine, Windsor

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mine. And so it's the source of talc at this particular point in time, and they are discussing the issues around the way that the company was handling the safety of the talc coming from the mine as it related to whether or not there was asbestos in the mine.

So let me stop you right there. You mentioned Windsor Minerals.

Was Windsor Minerals owned by Johnson & Johnson?

Α Yes, it was.

Okay. Specifically, I'd like to direct your attention, Dr. Plunkett, to the first paragraph of the memo, paragraph number 1, and it says, "It is our joint conclusion that we should not rely on the clean mine approach as a protective device for baby powder in the current asbestos or asbestiform controversy. We believe this mine to be very clean. However, we are also confident that fiber forming or fiber type materials could be found, thus the usefulness of the clean mine approach for asbestos only is over."

From your review of the documents and your understanding what was occurring at the time, what does that mean?

MS. BROWN: Your Honor, the question is, "What does that mean?" Speculation.

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THE COURT: Sustained to the form of the question.

MS. O'DELL: I will rephrase my question, Your Honor.

BY MS. O'DELL:

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Q What is your understanding of what was being referred to when they were talking about the clean mine approach, based on your review of the documents and testimony in the case?

MS. BROWN: Same objection, Your Honor.

THE COURT: I'll allow it.

THE WITNESS: Based the evidence I've seen and the discussion about this context for this document, this was the issue of the company using an approach in order to essentially try to prevent asbestos contamination from being within the talc that was being used for the baby powder. But they are now, in this document, recognizing the issue of fibers.

It's not just about asbestos, but there are also fibers there as well, and it's the idea that relying upon an approach where, if you're not fine -- you don't think you're finding asbestos in the mine, that doesn't mean that the powder is still safe when you have to look at the issue of

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fiber.

And there's other documents in this time period that are starting to discuss this issue as well. Later in this document, there is this issue we were talking about about what you can do instead and it talks about cornstarch.

BY MS. O'DELL:

Q I'm going to now direct your attention, Dr. Plunkett, to paragraph 3.

It says, "The current medical research is confirming that it is the particular shape, not chemical substance, which is harmful as such fiber like materials will be suspect."

Is that consistent with your opinion that it's part of the shape of the fiber, whether it's talc or asbestos, that makes the fiber toxic to the body?

A Yes, there had been scientific information and literature already accumulating showing that was the issue, why it is that fibers like asbestos can injure the tissue has to do with the size and the shape of the particle that gets into the tissue and what it can do.

Q Now, Dr. Plunkett, I'd like to direct your attention to page 2, paragraph B, specifically to the lower part of the paragraph.

It says, "These talcs," referring to the

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Page 693 1 Windsor mine's talcs, "contain widely varying amounts of 2 tremolite." 3 I'll stop there. Is tremolite asbestos? Tremolite is a fiber that is one of the 4 Α 5 asbestiforms, yes. 6 0 And it says --7 Your Honor, I object to the MS. BROWN: prelude by counsel. It's misreading the document. 8 9 THE COURT: It's up on the screen. It's in 10 front of the witness. MS. BROWN: She said something about Windsor 11 12 talc, Your Honor, and the sentence before that 13 shows that they are talking about packing 14 materials. 15 THE COURT: You can do that on 16 cross-examination. 17 MS. BROWN: Yes, Your Honor. 18 THE COURT: You may continue. 19 MS. O'DELL: Thank you. BY MS. O'DELL: 2.0 So I was reading, "These talcs contain widely 21 2.2 varying amounts of tremolite or fibrous talc." 2.3 Yes, that's what is listed. Α 24 And it says, "Our baby powder contains talc 0 25 fragments classifiable as fiber occasionally subtrace

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quantities of tremolite or actinolite are identifiable (optical microscope) and these might be classified as asbestos fibers."

Does this document confirm that J&J understood that their talcum powder, their baby powder, could have not only fibrous talc but asbestos?

Α Yes. And this is not the only document, but this is correct. This is one of the documents where they are really specifically keying in on the issue of fibers of talc.

Lastly, I'll direct you to page 3 of the document, Dr. Plunkett, to paragraph C. Do you see that?

Α Yes.

What is Johnson & Johnson saying about 0 cornstarch and whether it's a safer alternative to talc? And in your answer, if you'll just read what the document says, please.

Sure, so C says, "Cornstarch is obviously Α another answer. The product, by its very nature, does not contain fibers. Furthermore, it is assimilated by the body."

So does this confirm that they understood, one, that cornstarch was a safer alternative and it could be absorbed safely without a long-term harmful

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A Yes, that is correct.

Q Now, Dr. Plunkett, I'd like to change topics and turn to something that's called -- we talked about it earlier, the National Toxicology Program or NTP.

First, tell us briefly, what is the National Toxicology Program?

A So it's a program that is a sister agency to the FDA, and it is located within -- generally within the Department of Health and Human Services within -- just like FDA is, within the federal government. And it is a specific program within the federal government that's focused on toxicology testing.

It also provides resources for other parts of the government if there is an issue that could indicate a need to do a particular type of toxicology test in order to address a safety issue.

So it is a program that also is part of the overall federal government process for doing assessment of carcinogens. So they are involved in a federal program where they develop a listing of compounds that have been identified by the government in the U.S. as been carcinogens and it's called the report on carcinogens.

Q Okay. And did the National Toxicology Program

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Page 696 1 commission an animal study on -- that was evaluating 2 talc? 3 Yes, talc was nominated to the NTP for Α consideration and they performed some long-term animal 4 5 studies. It's one of the things NTP does a lot of, they have done over a hundred of them over the years. 6 7 And did you review that study and rely on it 0 in reaching your opinions? 8 I did. 9 Α 10 MS. O'DELL: Your Honor, at this time, I'd 11 like to display for demonstrative purposes 12 Plaintiff's Exhibit 2564. 13 THE COURT: You may. 14 MS. O'DELL: Thank you. 15 BY MS. O'DELL: 16 What is the title of the study, Doctor? 0 17 It's called Toxicology and Carcinogenesis Α 18 Studies of Talc. Carcinogenesis being a study of cancer 19 development in the animals. 2.0 And when was this published or made available 0 to the public? 21 2.2 Α In September of 1993. The studies were performed in the late 1980s. 23 24 0 Very briefly, tell us what the study involved. 25 Α So the study involved two species of animals,

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rats and mice, two common species that were used in this program to do cancer testing, and they treat the animals or expose the animals for their lifetimes. When I sav "their lifetimes," it's typically a two-year study. Getting to be two years of age for a rat or mouse is getting very old, so they have that two-year dosing paradiqm.

And the idea is to look at what happens to exposure in an animal that may be exposed throughout their lifetime, and it is meant to exaggerate the kind of exposures that you or I might receive. We might not get the same exposure every day, but we might be exposed continuously throughout our life to a chemical that might cause harm.

So in order to study that in the animals, they've adopted this protocol where they take the animals at a certain age, usually when they've reached sexual maturity, they dose them from that age on until two years. Then they sacrifice the animals and they take tissues and organs and samples and they look for the presence of tumors or lesions that are indicative of what's called a precancerous -- remember I talked about abnormal cells, they look for that.

In addition to doing the two-year studies, they typically report -- which they did here too --

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toxicology studies of shorter duration. So they pair up these shorter term studies that are anywhere from -- I forget, I have to look to tell you exactly how long, but usually a week or 14 days. They'll typically do a three-month dosing study, and then they use those studies to determine what dose they should select to give to the animals in the long-term study.

Because one of the principles of toxicology and exposure is the more you're exposed to the more likely you'll see a toxic effect. The longer you're exposed to it, the more likely you'll see a toxic effect, both how long and how high.

And so in order to make sure the animals lived two years, you don't want to give them too much that they'll die quickly. So you're trying to find a dose that allows you to dose the animals throughout their lifetime, but also maximizing the chances you might observe a toxicity to be able to know and then calculate based upon the data and determine based on the data what the response in a human may be. We try to extrapolate from the animals and say what might happen in a human.

MS. O'DELL: Gina, if I could ask you to go to the conclusion, which was, I believe, page 8 of the document.

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BY MS. O'DELL:

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What was the conclusion of the study? What Q did they find? What was the final report of their findings?

So in this paragraph, they report that in the rats -- by the way, I forgot to mention, they do both males and females because there can be differences in response to chemicals if you're a man or woman. So they look at males and females.

In the male and female rats, they saw a different response in terms of the level of evidence, but they saw tumors in both sexes of the rats. They did not see those tumors in the mice that were treated. They looked at male and female mice.

The rats, they report, if you look at the paragraph, that there was some evidence of carcinogenic activity of talc in the male rats and, in the female rats, if you go down to the next italic, there was clear evidence of carcinogenic activity with talc in the female rats. And there's different types of tumors being seen in different locations in the animals.

The female rats are seeing lung tumors and the male rats are seeing a tumor that is on the adrenal gland, which is a gland within our bodies, too, that controls a reaction called fight or flight. It secretes

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hormones that are stress hormones.

Q Following the publication of the NTP study, the animal study, what happened? What took place after this reporting of, in a study, talc can cause carcinogenic activity, particularly in female rats?

A So after this occurred, this spurred a lot of interest in the toxicology community with understanding what the implications of this might be based on what was already known in the literature. There had already been, at this time in the late '80s, reports in the literature of a relationship of ovarian cancer in women exposed to talc powders.

And then after this study, there are additional studies that start to appear in the literature where investigators then look at populations of people, women, exposed to talc body powders in their genital area and whether or not there was a relationship between that exposure and ovarian cancer.

It also spurred a look at lung cancer issues in workers that were working in industries where talc is either processed or talc is used. Talc is used an ingredient in variety of other types of consumer products in lower levels or in smaller amounts, but workers can be exposed.

So there was an interest in both the issue of

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lung cancer with inhalation exposure, but then also the issue of whether or not talc that gets into the body can cause cancer in other areas as well.

Q Was talc nominated as a potential carcinogen for the report on carcinogens, which is I think what you referred to?

A Yes. So after this report came about and the interest in the toxicology community about seven or eight years later, this chemical talc was nominated to the NTP for consideration in listing as a carcinogen in their report.

The Report on Carcinogens is an initiative that was put forth, I think, in the Carter administration to provide a program that would focus on making sure that the cancer-causing agents were identified and reviewed as needed based upon scientific evidence that may have accumulated or on exposures that appeared to be of a problem, for example, in different populations.

So talc was nominated to the Report on Carcinogens after this study, plus some of the other human studies that it showed lung tumors in workers that were exposed to talc in industry, as well as some of the studies shown that women exposed to talc had been developing ovarian cancer as well. So all of that

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information was part of why it was nominated. It wasn't just this study alone.

But this study was important because it was well controlled, large study that attempted to look at the biological basis because it had tissue samples, detailed analysis in the animals, doses that you could look at. So it was kind of a more rigorous scientific way to look at whether or not, in a living organism, talc could indeed cause cancer.

Q For the sake of time, Dr. Plunkett, were there two committees that review the evidence related to whether talc is a carcinogen within the National Toxicology program? And tell us just briefly about that.

A Within the Report on Carcinogens process, yeah, there are two committees of scientists that initially looked at this study and the other literature I mentioned, the reports of lung cancer in workers as well as the ovarian cancer cases, the reports in women. They looked at that -- it's called epidemiological evidence or human studies, in addition to this animal study, and they used it in an assessment of whether or not they thought that talc should be listed as a carcinogen.

These first two committees were just

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scientists from NTP and other sister agencies, and they voted to nominate it to go to the next step. So they found it, by a voting of the members, that indeed they thought that the compound should be listed.

So it went to the next level, which is the third group that makes it a more public process where these two are internal scientists at the agencies.

Q And just before you move on to the public phase, what was the vote of those two scientific committees in terms of whether it should be listed as a carcinogen?

A So I think the first vote was six to zero, six to list, zero to not list. And the other, I think, was seven to the two. So it ends up, when the two numbers are looked together, it was 13 to two. So the scientists, as both groups, 13 were voting to list it as a carcinogen and two were voting not to list it.

Q And when it moved to this period for public comment after the votes of those two committees to list as a carcinogen, what happened?

A So it went to the next step and it was deferred. So there was a public meeting that was held and scientists -- there's other scientists from outside the agencies that are looking at this now and there is also the opportunity for the industry to actually get

Page 704 1 involved, which is what happened in this case. And in 2 particular, after that meeting, that third step, the 3 compound was deferred. It means it wasn't listed at 4 that point in time and this was in 2000. Okay. And have you looked at the minutes from 5 that meeting that you're referring to, that public 6 7 meeting? I did. 8 Α 9 0 And is that part of your work to prepare your 10 opinions in this case? 11 Α Yes, it was. 12 Your Honor, at this time, I'd MS. O'DELL: 13 move into evidence Plaintiff's Exhibit 2569. 14 No objection, Your Honor. MS. BROWN: It shall be received without 15 THE COURT: 16 objection. 17 (The referred-to document was marked into evidence as Plaintiff's Exhibit 2569.) 18 19 BY MS. O'DELL: 2.0 Very quickly, did the meeting take place in 0 21 December of 2000? 2.2 А It did. 2.3 MS. O'DELL: Gina, if you will, please, turn 24 to page 16 of the document. 25

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BY MS. O'DELL:

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Q I want to direct your attention, Dr. Plunkett, to a paragraph that begins "Mr. William Kelly." Do you see that?

A I do.

Q Who is William Kelly?

A So he was a consultant that worked for at a company called The Center for Regulatory Effectiveness, and he had been working with Johnson & Johnson and the talc suppliers, as well as the CTFA that we talked about, the trade organizations, to develop a strategy to combat this listing, this issue of being proposed for listing of talc as a carcinogen. So he was the lead that was speaking at this meeting, and he had been working behind the scenes for a period of time. There's evidence and documents I've seen to show that he was working on behalf of the industry.

Q And in here, in the paragraph, it says,
"Mr. William Kelly Center for Regulatory Effectiveness."

Did he disclose that he was working on behalf of Johnson & Johnson and the talc supplier and others?

A He did not.

Q Would that have been an appropriate thing to do in a public hearing like that?

A Yes, that is. As a scientist, I would be

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expected to do that, and being that he was here at a meeting that was discussing science, yes, you need to disclose what it is you're talking about and whether or not what you're talking about has been an opinion that was or a statement that has developed with support from an industry group.

Document 2648-32

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And is one of the arguments that was put 0 forward by Mr. Kelly and others that talc shouldn't be listed as a carcinogen because, in the past, it had asbestos, but now it no longer has asbestos? Do you recall that?

Α Yes, that was the crux of his argument. That's correct.

And so was Mr. Kelly telling the committee that Johnson's baby powder or talc, talcum powder, no longer had asbestos? Was that one of the things he put forward to the committee?

Yes, he did. He said it no longer had Α asbestos and he was trying to say that the problem is that, in the past, all those studies that have been done would be talc that could have had asbestos in it, but theirs doesn't. So, as a result, he was challenging the studies as whether they were applicable to talc that was being produced at that time.

Q Was there evidence -- have you seen evidence

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from Johnson & Johnson, in the documents they produced, that would establish it wasn't true, that at this time period or any other, for that matter, that Johnson's baby powder did not contain asbestos?

- I have seen such evidence, that's correct.
- And you said the outcome was this was 0 deferred?
 - Α Yes.
 - And what does that mean? 0
- Α If you read the minutes in the discussion here, you'll see the scientists, after the public comments were made, felt that they didn't think they could make a decision on whether to list or not at that It was based upon this issue -- they discussed this in their comments or their back and forth -- on the issue of whether or not the talc issue was the presence of asbestos or was it the presence of talc.
- So in other words, did Johnson & Johnson, and 0 others in the industry, essentially create confusion in order to stop this process of having talc listed as a carcinogen?
- Α In fact, there is a document where that's their own words.
- 24 0 Did Johnson & Johnson celebrate when they were able to achieve this outcome?

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Again, there are documents and evidence in this particular case that show that's exactly was their reaction. This was what -- this is the -- the discussion in those documents will speak for itself, but essentially it is talking about a celebration of the result they were attempting to get, which was to stop the process of the listing.

PageID: 97356

0 Let me step back for a minute and just ask you, Dr. Plunkett: Was it clear from the NTP process and NTP study and other studies that you've mentioned, that the genital use of talcum powder was a hazard?

Yes, absolutely. That's a different consideration that is not being discussed in this document. Absolutely.

- Was that hazard ovarian cancer? 0
- The hazard was ovarian cancer. Α
- In your opinion, based on your understanding of the industry standards, did Johnson & Johnson act as a responsible company to protect women and consumers in the way they interacted with the National Toxicology Program?
 - Α No, they did not.
- Doctor, I'd like to turn now to discuss the 0 FDA, the Food and Drug Administration. And following the publication of the NTP study and some of the other

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Page 709 1 studies that were coming out at that time, in 1994, did 2 an organization by the name of Cancer Prevention 3 Coalition send a letter or petition to the FDA? Did 4 they do that? 5 Α Yes, they did. MS. O'DELL: Your Honor, at this time, I'd 6 7 like to move into evidence Plaintiff's Exhibit 8 2562. 9 THE COURT: Any objection? 10 MS. BROWN: No objection. It shall be received without 11 THE COURT: 12 objection. 13 (The referred-to document was marked into 14 evidence as Plaintiff's Exhibit 2562.) 15 BY MS. O'DELL: And Dr. Plunkett, is this the submission -- I 16 17 think they call it a Citizen Petition; is that correct? 18 Α Yes, Citizen Petition is a very specific type of submission that's allowed under the FDA regulations. 19 Any person here in the public, if they would like to do 2.0 21 that, can go and submit this type of document to request 2.2 an action from the agency. 2.3 And what did the Cancer Prevention Coalition 0 24 ask the FDA to do? 25 Α So they were asking the FDA, based upon --

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they have -- in the petition, they describe the evidence that they're looking at. They were asking for labeling for the particular products, if they were going to be still left on the market, the talcum powder causes cancer in laboratory animals and that frequent application in the genital area of women increases the risk of ovarian cancer.

So they were tapping into the two pieces of evidence that were relevant to what we just saw -- we saw discussed in 2000 by the NTP, the animal data as well as the human data that had accumulated, and this is 1994.

Q And was one of the bases for the Cancer Prevention Coalition, sometimes maybe referred to as CPC, but this organization, was one of the bases they sought a warning the presence of asbestos in talcum powder?

A Yes, that is specifically discussed in their petition.

- Q Did they ask for a specific warning?
- A I'm sorry?
 - Q Did they ask for a specific warning?

A Well, they asked for a warning, if you'll see what's on the screen, they asked for warning such as -- and so there was a quote for a specific language that

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they were asking for, yes, but they are couching it as a warning such as.

- And they were seeking to have a warning for 0 ovarian cancer, correct?
 - Absolutely, ovarian cancer.
- And let me ask you: I'm going to ask you 0 about who a gentleman is, John Bailey. Who is John Bailey?
- John Bailey, at this time period, was the acting director of the office of cosmetics, so it would be the office that is responsible for FDA actions related to cosmetic products ingredients. And he -since this was a petition about a cosmetic, he would be the responsible part of the FDA that the petition would be sent to for him to respond because it was a cosmetic and the cosmetic office would respond.
- And did, in fact, he send a response for the 0 Citizen Petition?
- Yes, he eventually did. He has a clock Α running and he did eventually do that.
 - MS. O'DELL: Your Honor, I want to move into evidence Plaintiff's Exhibit 2373.
- THE COURT: Any objection?
- 24 MS. BROWN: No objection.
- It shall be received without 25 THE COURT:

Page 712 1 objection. 2 THE CLERK: Moved into evidence. 3 (The referred-to document was marked into evidence as Plaintiff's Exhibit 2373.) 4 5 BY MS. O'DELL: Dr. Plunkett, is this the letter that John 6 7 Bailey wrote back to the Cancer Prevention Coalition 8 regarding the petition? 9 Α It is, yes. 10 0 And what's the date? The date is July 11, 1995, so it was within 11 Α 12 the allowable time period. It says that later down. 13 They have 180 days from the time the petition was filed, 14 the FDA does, to respond to the petitioner and that's 15 what he's doing. 16 This is July of 1995. And this time period 17 shortly before July of 1995, did John Bailey -- have you 18 seen documents that would demonstrate that John Bailey 19 met with representatives of Johnson & Johnson? 2.0 Α Yes. 21 Objection, Your Honor, leading. MS. BROWN: 2.2 THE COURT: Overruled. 23 Yes, there is evidence to show THE WITNESS: 24 that right before this, he had done that. 25

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BY MS. O'DELL:

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- Q And what was his decision as to how the petition would be handled?
- A It's highlighted there that he decided not to grant anything -- not grant the petitioner, the request, and the reasoning given was the limited availability of resources and other agency priorities.
- Q Okay. After this letter in 1995, did John Bailey remain with FDA?
- A For a period of time, yes, but then he left and he went to the CTFA.
- Q And the CTFA, we referenced it, but that's the Cosmetic, Toiletry, and Fragrance Association, correct?
- A Yes, he left the agency and went to the trade organization that was involved with the products that he, as a regulator, had oversight for.
 - Q In broad terms, is that a lobbying group?
 - A Yes, yes, you could call it that.
- Q As an employee of the Cosmetic, Toiletries, and Fragrance Association, did ultimately John Bailey become the person that was interfacing with the FDA about cosmetics?
- A Yes, that was his -- what happened after he left and went to CTFA. He had numerous interactions back with the FDA through that organization.

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Page 714 1 At some point -- the initial petition was in 2 1994. At some point, there was another petition very 3 similar, I believe later on. But for sake of time, did the FDA, at some 4 5 point years after, did they respond? And how many years did it take for the FDA to respond to the petition? 6 7 To this petition and another one that was filed very similarly in '08, it wasn't until 20 years 8 9 after 1994, 2014, before the FDA actually finally put in 10 a response to the original petition. MS. O'DELL: Your Honor, I'd like to move into 11 12 evidence Plaintiff's Exhibit 2010. 13 THE COURT: Any objection? 14 No, Your Honor, no objection. MS. BROWN: 15 THE COURT: It shall be received without 16 objection. 17 Admitted into evidence. THE CLERK: 18 (The referred-to document was marked into evidence as Plaintiff's Exhibit 2010.) 19 2.0 BY MS. O'DELL: 21 So what is the date of this response? 0 2.2 Α April 1, 2014. 2.3 And, Dr. Plunkett, did the FDA deny the 0 24 request for a warning? 25 Α Yes, they did.

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And if you'll look down to the lower half of the first page, the paragraph beginning after "careful review, " what does it say that the FDA concluded?

Α They say, in the last sentence there, that the FDA did not find the data submitted, so there was data submitted with the petition, that they presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.

And is conclusive evidence of a causal 0 association the appropriate standard to have been used for a cosmetic?

No, not based upon the 740.1 section that we've already presented. It's less than that. type of standard is the type of standard you apply to adding a warning to a drug.

And is the cosmetic standard is shall require a warning if a hazard may be associated; is that fair?

Α That is correct.

MS. O'DELL: And if you'll turn to page 2 of the letter, Gina, please.

BY MS. O'DELL:

0 You know, we mentioned you testified a few minutes ago that one of the bases for the petition was that talc contained asbestos. What did the FDA say in response to that particular concern?

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A So they actually went through a review of the asbestos issue with them and they talked about the fact that there had been some reports, and they go through it. But they didn't find the evidence conclusive that asbestos was still in products at that point in time.

Q And so if you'll jump to the bottom of the

page, the last sentence beginning review, "You" -- we're talking to the Cancer Prevention Coalition, "have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed."

Do you see that?

- A That is correct.
- Q They are talking to the Cancer Prevention Coalition, correct?
- 16 A That is correct.
 - Q And who had evidence that asbestos was contained in Johnson's baby powder in this time period?
 - A The company did.
- Q And had that evidence been provided to the FDA?
 - A Not that I'm aware of, no.
 - Q Let me ask you to turn, Dr. Plunkett, please, to page 5 of the document. And did the FDA include pertinent information about your opinions regarding talc

Page 717 1 being able to migrate to the ovaries and inflammation? Yes, it's in the paragraph that starts with 3 "while there exists." THE COURT: Folks, is everything okay? 4 5 JUROR: Yes, Your Honor. THE COURT: 6 Thank you. 7 You may continue. MS. O'DELL: Thank you. 8 9 BY MS. O'DELL: 10 Read to us the pertinent language, please, 0 11 Dr. Plunkett. 12 So is says, "While there exists no direct Α 13 proof of talc and ovarian carcinogenesis, the potential 14 for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable." 15 16 0 Thank you. 17 In following this letter, this was 2014, did 18 the FDA -- so this was 2014. After that, did the FDA 19 reach out to Johnson & Johnson and ask for information regarding the safety of talc? 2.0 21 Α They did. 2.2 What year was that? Q 2.3 T believe 2016. Α 24 And have you reviewed Johnson & Johnson's 0 response to that request from the FDA? 25

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	Page 718
1	A Yes, I have.
2	MS. O'DELL: Your Honor, at this time, I'd
3	like to move into evidence Plaintiff's
4	Exhibit 2531.
5	THE COURT: Any objection?
6	MS. BROWN: No, Your Honor.
7	THE COURT: It shall be received without
8	objection.
9	THE CLERK: Admitted into evidence, 2531.
10	(The referred-to document was marked into
11	evidence as Plaintiff's Exhibit 2531.)
12	BY MS. O'DELL:
13	Q Is this a letter from Johnson & Johnson?
14	A It is, yes.
15	Q And what's the date of the letter?
16	A This is March of 2016.
17	Q And who is Johnson & Johnson writing to?
18	A They are writing to the U.S. Food and Drug
19	Administration.
20	MS. O'DELL: And specifically, first
21	paragraph, please, Gina at the bottom.
22	BY MS. O'DELL:
23	Q What is the specific request
24	MS. BROWN: Counsel, this is not a redacted
25	copy that you have on the screen.

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Page 719 1 MS. O'DELL: I'm sorry. 2 BY MS. O'DELL: 3 This is Plaintiff's Exhibit 2531, and Gina did 0 4 a better job highlighting than I will, but this was 5 March of 2016 from Johnson & Johnson. What was the specific request that the FDA made of Johnson & Johnson? 6 7 It's the quote there, please -- they were asking for safety information related to the use of 8 9 talc, and they say, "Please provide all safety 10 literature and data regarding talc, including data in 11 support of the safety of this active ingredient and data 12 that shows potential harmful effects for this active 13 ingredient," and they gave them a deadline of 14 March 17th and that's what this letter is in response 15 to. 16 It is a letter from Jethro Ekuta, vice 0 17 president of regulatory affairs, North America Johnson & 18 Johnson Consumer, Inc.? 19 Α Yes, that's correct. Dr. Plunkett, this is a response to the FDA 2.0 0 21 request for information on talc; is that right? 2.2 Α That's correct. 2.3 And from Johnson & Johnson Consumer, Inc.? 0 24 Α That is correct. 25 Q Did they evaluate or provide information,

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Page 720 1 Johnson & Johnson provide information about the components or the constituents of Johnson's baby powder? 3 Yes, they do. Α 4 And if you would turn to page 12 of the 0 5 document, please, Dr. Plunkett. Α 6 Yes. 7 Do you see that? And they state here, "No asbestiform structures have ever been found during any 8 9 testing." 10 That's coming from Johnson & Johnson, correct? 11 Α That is correct. 12 And is that a true statement? Q 13 Α Based on the evidence I have seen, it is not. Had Johnson & Johnson found asbestiform 14 0 15 structures in their talcum powder for decades by 2016? 16 Yes, they had. А 17 So that's 2016. After 2016, let's fast 0 18 forward to 2019. 19 Did the FDA test Johnson's baby powder? Yes, they did. 2.0 Α 21 And what did they find? 0 2.2 Α They found some asbestos or fibrous structures in the talc. 23 24 And following that testing, what action did 0 25 the FDA -- following that testing of Johnson's baby

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powder and other cosmetic products, what steps did the FDA take?

- Α They asked for a recall of the products.
- What about -- if I could focus your attention 0 on the working group?
 - А I'm sorry.
- The working group's standpoint, what did --0 what steps did they take?

So after this finding, the FDA began a Α process to understand how widespread this was, and also to address the issues of the appropriate testing to be used by the industry to confirm that talc products were asbestos free. And that led to a gathering of experts in a workshop in February 2020, which is one that I attended.

From a toxicology perspective, this working group and what they were considering, why was it important for their consideration of fibers?

Α What was important about it in this workshop, they are specifically discussing and describing the importance of the structure and the size of the particles and the idea that the term elongated mineral particles, or EMPs, was an appropriate way to go about identifying hazards in these products based on the presence of certain specific types of fiber structures.

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And the working group -- well, the workshop, that particular topic is discussed, the idea that there is more than just asbestos as a term that is relevant to the safety or the hazard posed by products that may contain these certain kinds of fibrous structures or fibrous elements within them.

And did that working group that was considering these questions include some of the leading scientists within the government as it relates to asbestos and other fibrous minerals?

Yes, they brought people from a variety of government agencies, experts in relevant fields. example, they have someone from the U.S. Geologic Survey to speak to mineralogy. They had toxicology people from They had NIOSH people, worker safety people there. They had experts drawn from different areas.

They had FDA that spoke as well talking about the need to identify an appropriate approach in order to ensure that, in humans that may be exposed to products regulated by FDA, were indeed being exposed to products that didn't pose that hazard of having the presence of these kinds of fibers in them.

And because of the health concerns associated 0 with fibers, was the FDA and other governmental agencies attempting to determine the best way to test for

Page 723 1 cosmetics for the presence of asbestos? 2 Yes, that's something that developed out of 3 this workshop and this work by this combined government 4 cooperative assessment that was being done. That's 5 exactly right. During the opening statement, counsel for 6 7 defense mentioned testing that had been done on 8 cosmetics in 2021 by the FDA, and I want to make 9 something clear: Are you aware of what was tested? 10 Α Yes, I am aware of testing that was done in 11 2021 by FDA. 12 Was Johnson's baby powder tested? 0 13 Α No, Johnson's baby powder was not one of the 14 products that was tested in 2021. 15 0 And so just in summary of discussion about the 16 FDA and interaction we've been talking about --17 THE COURT: I don't know what you mean by 18 "summary," but certainly she's not going to tell us 19 everything she's already said. 2.0 MS. O'DELL: No, sir, not at all. Thank you, 21 Your Honor. 2.2 BY MS. O'DELL: 2.3 Interacting with the FDA, Dr. Plunkett, did 0 24 J&J, on regulatory perspective, act as a responsible 25 company to protect consumers?

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Page 724 1 I don't believe they did, no. Α Q Now let's turn to --3 THE COURT: It's 4:30 p.m. I said we'd stop at 4:30 p.m. today. 4 5 Ladies and gentlemen, we are going to be in recess for the day. We'll be back in session 6 7 tomorrow morning at 9:15 a.m. 9:15 a.m. -- okay, 9:30 a.m. 8 9 JUROR: Can I say something --THE COURT: One minute, ma'am. 10 11 But I need you all to be here as close to 9:30 12 as possible, please. We lost about an hour today 13 because we got started a little later, and I'm 14 abbreviating my calendar so that I make sure I'm 15 here at 9:30 a.m., so I need you all to do 16 everything you possibly can to please be here. 17 Remember, the goal is to try and get you the case 18 as quickly as possible, but the only way that works 19 is that we all plan on being on time, okay? Remember, you cannot discuss the case amongst 2.0 21 yourself or with anyone else. No independent 2.2 research about the case. No posting, social media 2.3 or anything like that. 24 Have a good evening and we will see you 25 tomorrow morning at 9:30 a.m.

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Ma'am, you can stay behind if you want to ask me a question. You can hand the note pads to Rod as you head out.

JUROR: I was here today 9:30. I come all the way from Aventura, one hour, 45 minutes to come I came here stayed, again, 45 minutes wait for other people to come here.

THE COURT: Ma'am, I can't get started until all ten of you are present.

JUROR: I understand, but why I am here that other people don't?

THE COURT: We are going to encourage everyone to make sure you are on time, and I'm sure everybody is doing the --

JUROR: It's very sad.

THE COURT: -- best they possibly can. I'll see you all tomorrow at 9:30 a.m. Thank you.

(The jurors exited the courtroom.)

Okay. Let's be honest, we know THE COURT: she is going to be a problem throughout the whole proceeding, so we've just got to kill her with kindness, just smile and say good morning, how are you, and hope that she'll relax a little bit.

All right. You can step down. You are on the witness stand. You should not discuss your

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testimony with anyone.

I went through -- at least I got through three-quarters, if not a little more, of Hopkins. I have a question on Hopkins. He is the corporate representative?

MS. BROWN: He is not. In this case, Your Honor, he gave deposition testimony as the corporate representative in the past.

THE COURT: So this is not for this case? MR. OLIVER: It is for this case, Your Honor. They put up a number of different corporate representatives over time. For example, one of them I deposed, we submitted some of her testimony, Dr. Nickelson.

Dr. Hopkins, we didn't redepose him but he gives some specific testimony about the admissibility of the documents that we need. So there are multiple -- they put up multiple corporate representative reps during this whole litigation and we are using them for different purposes. They actually replace --

I don't know if I've heard that. THE COURT: Let me make sure I understand. Did you ask -- you didn't -- when I say "you," I mean your team.

Your team is not the one asking these

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of?

Page 727 1 questions? MR. OLIVER: For Hopkins, no. For Nickelson, 3 yes. THE COURT: 4 I haven't read -- I've only read 5 Hopkins. And the reason is because he's a corporate rep, and so I don't think he can give 6 7 expert opinions. The issues isn't what he 8 personally thinks about a particular topic, it's 9 him speaking on behalf of Johnson & Johnson. 10 And so there are several times during this 11 deposition, latter part of the deposition, where he 12 is being asked about his opinion as to certain 13 things. And I'm not saying he's not qualified to 14 do it, I'm just saying that wasn't his purpose at 15 that deposition. 16 He was there as a corporate representative. 17 And so if he said what Johnson & Johnson did, what 18 Johnson & Johnson knew, and replied to the 19 documents in that context, I guess I would get it. 2.0 But it looks as if he was actually being asked, "Do 21 you know what this is?" And, "What do you think 2.2 about this?" 23 And I don't think -- and so I sustained all of

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those, but is there something I need to be aware

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MS. BROWN: Well, Your Honor, he was a long-time employee of the company, and so he has a lot of personal knowledge about talc safety issues. So oftentimes -- and I'd have to look at what they designated from -- he went up in his personal capacity as well.

And on both sides, people asked him questions, not just as the corporate rep, but as Dr. John Hopkins in his personal capacity.

THE COURT: Well, the objections that I've read, it appeared to me that they were going through a lot of documents that -- and I did ask the question. I said, well, why -- is it Blount? And then there was these documents about the mine. And so my first question was -- I wrote a question on there. I said, okay, whose documents are these? I was like, why is he able to testify to the documents?

And then later, when I read, it became clear that these were -- they were their documents, but it was done on behalf of -- or it was done in conjunction with Johnson & Johnson; is that fair?

MS. BROWN: Well, he would have known about Blount during the time period he was working there, and if something was taking place in the '90s when

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Page 729 1 he was a toxicologist at the company. THE COURT: So the mining and all that, that's 3 all part of that? 4 MS. BROWN: Yes, sir. 5 THE COURT: I overruled those objections. only asking that question because I didn't 6 7 understand how he was being presented. Okay. I guess I'll finish sometime tomorrow 8 9 morning on -- if you want what I got, I can give 10 you what I got and then I can finish the last few 11 pages tomorrow. 12 MR. OLIVER: Your Honor, is this a good time 13 to hear an issue regarding some of the 30(b)(6) 14 testimony since we're on that subject? It's not 15 about the specifics, but we have an argument --16 this is not a good time? 17 THE COURT: No, I don't want to hear about it. 18 I'm going home. MR. OLIVER: Can we be heard, Your Honor? 19 THE COURT: At some point, it could be heard 2.0 21 but just now is not the time when it's going to be 2.2 heard. What about my jury instructions? 2.3 MR. RAYFIELD: We are working on those. THE COURT: Stop telling me that. Let me tell 24 25 you why I want the jury instructions. I would

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think you all would want me to have the jury instructions because, by me having the jury instructions, I know all the issues that are in the case. I normally read jury instructions before the trial even begins, and you all haven't -- you've given me your proposed jury instructions. But I'm asking you to get together and narrow them into one set.

By the way, I don't need the standard, I need the substantive instructions because that is, to me, is the heart of the case. That way when I'm ruling on things, I don't need to ask, maybe, so many things. It can just be -- I can know some things by the jury instructions that you're proposing.

MR. RAYFIELD: That's exactly what we're working on. It's a single document with red lines noting each of the parties different instructions so it will be clear which side is proposing what.

THE COURT: You all do know that was due before we started the trial.

MR. RAYFIELD: If I misunderstood that, I'm sorry. I thought each side's proposals were due at the start of trial.

THE COURT: No, no, I don't even like -- I

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won't even accept -- because that's more work for me. I mean, why am I going to read the plaintiff's jury instruction and then read the defendant's jury instructions and I just want to see plaintiff proposed jury instruction, you red line them and say we object -- these are the ones we agree with, these are the ones we disagree with, and here are the ones that they didn't even submit that we want added.

That, to me, makes it so much easier for the trial court rather than me having to flip through and find out, okay, I read yours that's a duplicate, I read that. But as soon as you can get them to me -- I'm talking to you, but obviously I'm talking to the plaintiff as well. As soon as you can get me the jury instructions, I need the jury instructions.

Okay. Anything else that you want to bring to my attention that requires less than five minutes?

MS. BROWN: No, Your Honor.

THE COURT: See you all tomorrow morning at -if you get here at 9:15, if I can finish my motion
calendar -- I literally went through every motion
on my motion calendar and I already wrote what I'm
going to do. So hopefully I can go through the

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Page 732 1 motion calendar a little quicker, I think somebody 2 is going to have something to say about that, some 3 of the lawyers who appear, but I went through every motion on my motion calendar to make sure I can get 4 5 through it by 9:15. So if you get here by 9:15, that will give you 6 7 some time, and hopefully we won't have to wait for the jurors. We'll be in recess until tomorrow 8 9 morning at 9:15 a.m. 10 (The proceedings recessed at 4:40 p.m.) 11 (Continued in Volume III.) 12 13 14 15 16 17 18 19 20 21 22 23 24 25

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Page 733 1 CERTIFICATE 2 3 I, CHRISTINE SAVOUREUX-MARINER, Florida 4 Professional Reporter, certify that I was authorized 5 to and did stenographically report the foregoing proceedings and that this transcript is a true 6 7 record of the proceedings before the Court. I further certify that I am not a 8 9 relative, employee, attorney, or counsel for any of 10 the parties, nor am I a relative or employee of any 11 of the parties' attorney or counsel connected with 12 the action, nor am I financially interested in the 13 action. 14 Dated this 14th day of February, 2024. 15 16 17 CHRISTINE SAVOUREUX-MARINER 18 Florida Professional Reporter 19 20 21 22 23 2.4 25